Is early rehabilitation after total knee replacement better with Periarticular injection or Epidural Bupivacaine?

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF **M.S BRANCH –IV (ORTHOPAEDICS)** EXAMINATION OF THE TAMILNADU DR.MGR. MEDICAL UNIVERSITY TO BE HELD IN **APRIL 2015**

CERTIFICATE

I declare that this dissertation entitled "**Is early rehabilitation after TKR better with Periarticular injection or Epidural Bupivacaine?**'' submitted towards fulfilment of the requirements of the Tamil Nadu Dr. M.G.R. Medical University for the MS Branch IV, Orthopaedics examination to be conducted in April 2015, is the bonafide work of **Dr. Ajith.K,** postgraduate student in the Department of Orthopaedics, Christian Medical College, Vellore.

Dr. Ajith.K

Postgraduate Student (M S Orthopaedics)

Register Number: 221312401

Department of Orthopaedics

Christian Medical College

Vellore.

CERTIFICATE

This is to certify that the dissertation entitled **'Is early rehabilitation after TKR better with Periarticular injection or Epidural Bupivacaine?'** is a bonafide original work of **Dr Ajith.K,** submitted in partial fulfillment of the rules and regulations for the MS Branch IV, Orthopaedics examination of The Tamil Nadu Dr. M.G.R Medical University to be held in April 2015.

Dr. Alfred Job Daniel

Principal,

Professor,

Department of Orthopaedics

Christian Medical College,

Vellore

CERTIFICATE

This is to certify that the dissertation entitled **'Is early rehabilitation after TKR better with Periarticular injection orEpidural Bupivacaine?'** is a bonafide original work of **Dr Ajith.K,** submitted in partial fulfillment of the rules and regulations for the MS Branch IV, Orthopaedics examination of The Tamil Nadu Dr. M.G.R Medical University to be held in April 2015.

Dr. Vernon Lee

Professor and Head

Department of Orthopaedics

Christian Medical College,

Vellore

CERTIFICATE

This is to certify that the dissertation entitled **'Is early rehabilitation after TKR better with Periarticular injection or Epidural Bupivacaine?'** is a bonafide original work of **Dr Ajith.K,** submitted in partial fulfillment of the rules and regulations for the MS Branch IV, Orthopaedics examination of The Tamil Nadu Dr. M.G.R Medical University to be held in April 2015.

Dr. Pradeep Poonnoose
Professor & Thesis Guide
Department of Orthopaedics
Christian Medical College,
Vellore

turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	221312401.ms Orthopaedics Ajith.K
Assignment title:	TNMGRMU EXAMINATIONS
Submission title:	Is early rehabilitation after total knee r..
File name:	CONTENTS.docx
File size:	2.02M
Page count:	109
Word count:	13,883
Character count:	75,768
Submission date:	10□D□2014 12:23PM
Submission ID:	457444716

Is early rehabilitation after total knee replacement better with Periarticular injection or Epidural Bupivacaine?

Is early rehabilitation after total knee replacement better with Periarticular injection or Epidural Bupivacaine?

ORIGINALITY REPORT

15%	11%	9%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	accweb.itr.maryville.edu Internet Source	2%
2	www.ifna-int.org Internet Source	2%
3	www.kneesociety.org Internet Source	1%
4	pt.umaryland.edu Internet Source	1%
5	www.nysora.com Internet Source	1%
6	Submitted to Higher Education Commission Pakistan Student Paper	<1%
7	Javad Parvizi. "Multimodal Pain Management After Total Joint Arthroplasty", The Journal of Bone and Joint Surgery (American), 06/01/2011 Publication	<1%
8	medlibrary.org	<1%

OASISCON 2014

OASISCON 2014....PALAKKAD....OASISCON 2014....PALAKKAD

13th Annual Conference of Orthopaedic Association of South Indian States

15-17 August 2014, Palakkad, Kerala

Certificate

This is to certify that in the Annual Conference of OASIS - 2014, Palakkad, Kerala

Dr. K Ajith ..... has

presented a **Paper** titled How effective is periarticular drug infiltration in providing pain relief following total knee replacement

Dr.K.R. Thyagarajan	Dr. R. Ravisankar	Dr. P.V.P. Nair	Dr. Vasudevan P.N.	Dr. Tajan P.J.
President - OASIS	Secretary General - OASIS	Organizing Chairman	Convenor	Organizing Secretary

ACKNOWLEDGEMENTS

I wish to express my heartfelt thanks to my guide Dr Pradeep Poonnoose, Professor and thesis guide, Department of Orthopaedics, Christian Medical College and Hospital, Vellore for his hard work, sincere support, guidance and encouragement in conducting this study and preparing this dissertation. I am also extremely thankful to my co-guides Dr.Anil Thomas Oommen, Professor, Dr. Vignesh Prasad, Associate Professor, and to Professor Dr. Vernon Lee, Professor and Head of the department of Orthopaedics for their expert advice, guidance and support throughout the study.

I would like to thank Dr. Sajan Philip George, Professor, Department of Anaesthesia for his persistent contribution towards the study. I am grateful to Dr.Jeyaseelan, Department of Clinical Epidemiology for his efficient guidance in sample size calculation and interpretation of results. .

I am also extremely thankful to all my friends and colleagues from the Department of Orthopaedics for helping me in collecting the samples and for their help in completing the study.

I would like to thank the Fluid Research Committee, CMC Hospital for granting me permission for conducting this study.

Last, but not the least, a special thanks to my family for their support throughout my study.

CONTENTS

ABSTRACT

INTRODUCTION

AIMS & OBJECTIVES

REVIEW OF LITERATURE

MATERIALS & METHODS

RESULTS & ANALYSIS

DISCUSSION

LIMITATIONS

CONCLUSIONS

BIBLIOGRAPHY

APPENDIX

1. Institutional review board (IRB) clearance form

2. Proforma

3. Anti coagulation protocol

CONSENT FORMS

PATIENT INFORMATION SHEET

DATA INFORMATION SHEETS

ABSTRACT

ABSTRACT

Title of the Abstract: Is early rehabilitation after total knee replacement better with Periarticular injection or Epidural Bupivaccaine?

Department: Orthopaedics

Name of the candidate: Ajith. K

Degree and subject: MS Orthopaedics

Name of the Guide: Prof. Dr .Pradeep poonnoose

Objectives: Assessment of efficacy of periarticular injection of a cocktail of analgesic drugs in pain reduction after total knee replacement and its comparison with the effectiveness of epidural infusion of bupivaccaine.

Methods: The study was a randomized control trial. Patients undergoing unilateral total knee replacement were included in the study. After preoperative assessment patients were randomized into two groups – one receiving periarticular injection of a cocktail of analgesic drugs, and the other receiving epidural bupivaccaine infusion for pain control. Post operative pain scores were noted on day1, day2, day3 and day10 along with the range of motion. Consumption of morphine and functional rehabilitation were also assessed and statistically analyzed using a repeated measure ANOVA.

Results: Patients who received the pericapsular injection of drugs had significantly better pain relief compared to epidural group in the immediate postoperative period. The functional rehabilitation was faster in those who received the pericapsular injection, but by the 10 post op day, there was no difference in the functional ability or pain relief. Range of motion was not significantly affected by the modality of pain control. There were less anaesthesia related side effects like nausea, pruritis, vomiting and urinary retention in those who received pericapsular injections.

Key words: Analgesic cocktail, Post operative analgesia, Epidural anaesthesia, Total knee replacement

INTRODUCTION

INTRODUCTION

Pain associated with major operations like total knee replacement (TKR) is quite considerable. Postoperative pain after Total Knee Arthroplasty (TKA) is a major concern to patients and the best technique to control pain is still controversial. Adequate pain relief is essential for early mobilization and good functional recovery. Modalities for postoperative pain relief include various combinations of systemic and/or regional analgesia with or without opioids.

In our institution, the current method of pain control after a TKR is with epidural anaesthesia. Other drugs including NSAIDs (Tab. Aceclofenac) and subcutaneous morphine are also used for pain control. Due to the negative effects of parenteral opioids and infusions, other multi modal approaches that provide adequate analgesia while minimizing opioid related side effects have been proposed. In this study we aim to compare the efficacy of the current method of pain control using epidural infusion of Bupivacaine with a multimodal approach using pericapsular injection of an anaesthetic cocktail of drugs including Ropivacaine, Noradrenaline, Depomedrol, Morphine and Ketorelac, coupled with oral NSAIDs, IV Paracetamol and Perioperative Pregabalin. Relief of pain will be monitored post operatively, and functional recovery will be monitored by observing the duration taken to complete a core set of functional goals.

AIMS & OBJECTIVES

AIMS & OBJECTIVES

AIMS:

To study the efficacy and safety of a Periarticular analgesic cock tail injection for early rehabilitation after a total knee replacement.

OBJECTIVES:

A) To assess the effectiveness of the periarticular injection of an analgesic cock tail in promoting early functional recovery.

B) To assess the effectiveness of the periarticular injection of an analgesic cocktail of drugs in the reduction of pain during the immediate post operative period , and comparing the outcome to the current treatment regimes currently being used to control pain in our institution – i.e. epidural infusion of Bupivacaine.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Pain control after total knee replacement

The management of osteoarthritis has primarily been directed towards pain management with the use of analgesics. Physical measures as moderate exercise and diet control for weight reduction in case of overweight people have been recommended. The medications used over time ranges from acetaminophen to opiod analgesics. Intra articular injections of corticosteroids, hyaluronic acid and platelet rich plasma also have been used for the management of osteoarthritis of the knee. It has been suggested that multimodal intervention would help in reducing the pain in case of osteoarthritis.

In cases where these conservative modalities are ineffective or where the deformity is pronounced surgical treatment is required. The surgical modalities of treatment include joint arthroplasty and resurfacing.

Pain associated with major operations like total knee replacement (TKR) is quite severe. More than half of these patients receive sub optimal pain control and may experience severe pain in the early post operative period. Adequate pain relief is essential for early mobilization and physiotherapy. Control of post operative pain could also reduce hospital admission days and re admissions. Several therapeutic methods have been used to control pain and improve function. These include combinations of systemic and/or regional analgesia with or without opioids like patient controlled analgesia, femoral nerve blocks, epidural infiltration and periarticular infiltration.

In our institution, the current method of pain control after a TKR is with epidural anesthesia. While this is effective, it is an invasive procedure, and necessitates restricting the patient's mobility till the epidural lines are removed.

Like the spinal, epidural anaesthesia produces a reversible loss of sensation and motor function with the only difference that the drug is injected in to the epidural space. Because of this larger doses are needed and should be monitored to avoid toxicity. Block can be given at the cervical, thoracic, lumbar or sacral (caudal) levels. This technique can be used for operative analgesia, post operative pain control and chronic pain management. Drug can be infused continuously using an infusion pump, can be given as a single shot or intermittent boluses. Epidural catheters may be left in place and allows the versatility to extend the duration of post operative analgesia and anaesthesia by injection of additional anaesthetic. Though it is easy to perform (though it takes a bit more practice than spinal anaesthesia) it has got a higher risk of failure and is slower in onset. But the anaesthesia is reliable and provides excellent operating conditions. Compared to general anaesthesia, with this we have a patent airway, fewer pulmonary complications, faster return of gastrointestinal function and decreased incidence of deep vein thrombosis and pulmonary emboli.

Absolute contra indications for epidural include

- ☐ Patient refusal
- ☐ Infection at the site of injection
- ☐ Coagulopathy

- ☐ Severe hypovolaemia: Not to be used in patients who are hypovolaemic or severely dehydrated. Patients should be pre-hydrated with 0.5 – 1 liter of crystalloid solutions (i.e. Ringers lactate) immediately prior to the block.
- ☐ Increased Intracranial pressure
- ☐ Severe Aortic Stenosis
- ☐ Severe Mitral Stenosis
- ☐ Ischemic Hypertrophic Sub-aortic Stenosis

Relative contra indications include

- ☐ Sepsis
- ☐ Uncooperative patients
- ☐ Pre-existing neuro deficits/neurological deficits
- ☐ Demyelinating lesions
- ☐ Stenotic valvular heart lesions (mild to moderate Aortic Stenosis/Ischemic Hypertrophic Sub-aortic Stenosis)
- ☐ Severe spinal deformities

Mechanism of action: On administration at a physiologic distance several barriers prevent spread of local anaesthetic to the intended site of action, which in turn requires larger volumes of anaesthetic. The intended targets are the spinal nerves and associated nerve roots. Dura mater acts as a modest barrier between the epidural space and spinal

nerve and nerve roots.The venous rich epidural space absorbs the majority of the solutions systemically. Epidural fatty tissue acts as a reservoir and only the remainder reaches the spinal nerve and nerve roots. Local anaesthetic injected into the epidural space moves in a longitudinal and horizontal manner. Horizontally the local anaesthetic spreads through the intervertebral foramina through the dural cuff via the arachnoid villa and into the CSF through arachnoid granules. Block occurs at the mixed spinal nerves, dorsal root ganglia, and to a small extent the spinal cord.

Compared to spinal, epidural takes 6-8 times the dose of a spinal anaesthetic to create a comparable block. This is because

- The nerves seen in the epidural space are large mixed compared to the subarachnoid space.
- Local anaesthetics must penetrate arachnoid and dura mater barriers.
- Local anaesthetics are lipid soluble and will be absorbed by tissue and epidural fat.
- Epidural veins absorb a significant amount of local anaesthetic with blood concentrations peaking in 10-30 minutes after a bolus.

Alpha-1 globulins bind the long acting amides, which have a high affinity for local anaesthetics but become rapidly saturated. These amides are metabolized in the liver and excreted by the kidneys. The esters are metabolized by pseudo cholinesterase so rapidly that there are rarely significant plasma levels.

Factors Affecting Height of Epidural Blockade

- ☐ Local aesthetic volume: 1-2 ml of local anaesthetic per dermatome

- ☐ Age: As age advances the dosage decreases due to changes in size and compliance of the epidural space
- ☐ Patient's height: Shorter the patient the less local anaesthetic is required.
- ☐ Gravity: A sitting patient will have more local anaesthetic delivered to the lower lumbar and sacral dermatomes. But this is not as pronounced as in spinal.

Local Anaesthetics used for Epidural Anaesthesia:

Before choosing a particular local anaesthetic, points to consider include an understanding of its potency and duration, surgical requirements, duration of surgery and the postoperative analgesic requirements. According to the duration of action these can be categorized into short acting (2-chloroprocaine), intermediate acting (lidocaine and mepivacaine) and long acting (bupivacaine, etidocaine, ropivacaine, levobupivacaine).

There were several cardiac arrests due to inadvertent intravascular injection of bupivacaine in obstetric patients. Bupivacaine (as well as etidocaine) are more likely to impair the myocardium and conduction system with toxic doses than other local anaesthetics. Bupivacaine has a high degree of protein binding and lipid solubility which accumulate in the cardiac conduction system and results in the advent of refractory re-entrant arrhythmias. Ropivacaine is a local anaesthetic drug belonging to the amino amide group. The name ropivacaine refers to both the racemate and the marketed s-enantiomer. Key advantage of ropivacaine over bupivacaine is that in doses for analgesia there is excellent sensory blockade with low motor blockade and it is less cardio toxic. Ropivacaine is indicated for local anaesthesia including infiltration, nerve block, epidural

and intrathecal anaesthesia in adults and children over 12 years. It is also indicated for peripheral nerve block and caudal epidural in children 1–12 years for surgical pain. It is also sometimes used for infiltration anaesthesia for surgical pain in children. Ropivacaine is often co-administered with fentanyl for epidural analgesia, for example in pregnant women during labour. Anne Weber et al [1] in 2005 after their study to determine the optimum dose of ropivacaine for perioperative peripheral analgesia in total knee replacement patients reported that 20mL of ropivacaine 0.5% was the most appropriate dose for perioperative analgesia in these cases.

Epidural additives like epinephrine will increase the duration of action of all epidurally administered local anaesthetics. Addition of fentanyl will accelerate the onset of analgesia and create a more potent/complete block to few. Sodium bicarbonate can be added to lidocaine, mepivacaine, and 2-chloroprocaine.Addition will increase the amount of free base which increases rate of diffusion and speeds onset.

Several other techniques for postoperative pain control such as patient controlled analgesia, femoral nerve blocks, and periarticular injections of medication have been reported.

Femoral nerve block historically known as 3 in one block, blocks the femoral, lateral femoral cutaneous and obturator nerves. The injection is given paravascularly in the femoral crease. It provides analgesia to anterior thigh (flexor muscles of hip and extensor muscles of knee).This is an ideal nerve block for surgeries of knee. For complete

lower extremity analgesia femoral nerve block should be combined with a sciatic nerve block

The landmarks for the femoral block include the femoral crease and femoral artery pulse. This technique is easy to master and carries very low risk. In addition to the surgical anaesthesia it is useful for postoperative pain management also especially in cases of surgeries of thigh and knee.

The femoral block anaesthetizes the skin and muscles of anterior thigh and most of knee and femur joint.

A standard regional anaesthesia tray is prepared with the following equipments:

1. Sterile towels and gauze packs
2. 20ml syringe with local anaesthetic
3. 3ml syringe with local anaesthetic for skin infiltration
4. 5cm, 22 gauge short bevel insulated stimulating needle
5. Peripheral nerve stimulator
6. Sterile gloves and marking pen

This technique is associated with minimal patient discomfort. This is because it passes only through the skin and adipose tissue of the femoral inguinal region. Still patients may feel uncomfortable as they feel exposed during palpation of femoral artery. In such cases sedation might offer patient comfort. Usual onset time for the block is 15 to 20 minutes depending on the type of anaesthetic and its volume and concentration. Loss

of sensation of the skin over medial aspect of leg below the knee is the first sign of onset of action.

Continuous femoral block is a similar technique, but the needle is inserted at a lower angle so as to facilitate the threading of a catheter. Following the initial bolus of the anaesthetic 0.25% ropivaccaine is used for continuous infusion. This is maintained at 5mL/hour. The armamentarium includes a catheter kit along with the instruments for a usual femoral block.

The common complications encountered in this technique include infections, hematoma, vascular puncture and nerve injury. The patient will not have weight bearing capacity on the blocked extremity. This has to be explained to the patient to avoid the risk of falls.

While femoral nerve blocks are effective in pain control, the possible quadriceps weakness could delay the rehabilitation and ambulation [2]. It was mentioned by Parvizi et al [2] that the primary concern about nerve blocks is the chance of developing neurological sequelae including permanent nerve damage. They suggested that multimodal pain management modalities have a safe side effect profile. These techniques might help reduce the opiod related side effects as post operative delirium.

Patient controlled analgesia includes methods that allow a patient in pain to control and administer medications required for pain relief. The most common form in this category is the oral, over the counter pain killers. Pain has been described as having a

tissue damage component and emotional component. The feeling of control over one's medication helps to alleviate the emotional factor associated with pain.

In hospital atmosphere the patient controlled analgesia usually refers to intravenous or epidural analgesia.

Intravenous patient controlled analgesia uses an infusion pump that is electronically controlled. This machine will deliver a pre-programmed dose of the analgesic when the patient presses a button. In some cases the machine is set to deliver a continuous slow flow of the medicine and additional doses are self administered by pressing a button. This is commonly used in end stage cancer patients and in post operative pain management. With this type of analgesia the caregiver should take care to program the analgesia in such a manner that overdosing is avoided. This is of extreme importance as this is commonly used for narcotic administration. In case of pre-programmed schedule the drug is released only at a set interval and the machine will not operate if the button is pressed sooner. This is commonly known as the lockout period. The usual lock out interval is about 20 – 30 minutes.

The patient controlled epidural analgesia administers the drug in a similar manner, but to the epidural space. This is done by infusion pumps or intermittent boluses. This method is usually used in managing post operative pain, by women in labour and terminally ill cancer patients.

Other routes of patient controlled analgesia are nasal, inhaled and transcutaneous.

The main advantage of this method is that pain is relieved faster as the drug administration is controlled by the patient. It is also seen that patient controlled analgesia reduces the intake of other medications.

Disadvantage is that there might be chances of over dose or reduced dose if the device is not programmed. Some individuals who are confused might not be able to master the technique of self administration. People who lack manual dexterity also might be unable to operate the device properly. Critically ill patients also might not be able to use this system.

A patient for whom the PCA is advised should

1. Be willing to use it
2. Be able to use it
3. Be physically able to press the button

Similar to this is the PCA by proxy where the pump is activated by anyone other than the patient. This is mainly found to be unauthorized. Hence Authorised agent controlled analgesia is recommended where trained individual is allowed to operate the pump in cases where the patient is not in a position to operate the mechanism. There are two varieties of the authorized agent controlled analgesia namely Nurse controlled analgesia and Care giver controlled analgesia. These should be programmed by an anaesthetist or member of pain control service.

Singelyn FJ et al [3] comparing patient controlled analgeisa, continuous three in nerve block and continuous epidural analgesia in 1998 suggested that the 3 in one block to be adopted as the technique of choice as it had fewer side effects, better pain relief and faster rehabilitation.

Chaumeron A [4] compared the effectiveness of femoral nerve block and periarticular injections in patients who underwent total knee arthroplasty and reported that the periarticular group reported less pain and less opioid consumption in the immediate post operative period. The quadriceps function was better in the periarticular group as this technique provide pain control along with avoiding the motor block that is seen with the femoral nerve block.

Kerr DR and Kohan L [5] in 2008 reported the use of local infiltration of a cocktail of drugs in 325 cases that had total hip replacement, hip resurfacing and total knee arthroplasty. A mixture of ropivacaine, ketorelac and adrenaline was infiltrated into the tissues around the surgical field. The patients reported good pain control, early mobilization and shorter admission periods. They also reported that no morphine was needed for pain control in two thirds of the patients after surgery.

Aditya V.Maheswari et al [6] in 2009 conducted a study on pain management in patients who underwent total hip and knee arthoplasty and suggested multimodal approaches for pain control. They emphasized the use of local, periarticular injections and minimizing the use of parenteral narcotics. They used a cocktail comprising mainly

of bupivaccaine along with morphine, epinephrine, methyl prednisolone acetate and cefuroxime for the periarticular injections. Though the use of parenteral narcotics have not been entirely discarded they conclude that the multimodal approach with local periarticular injections reduce complications as the unwanted side effects of narcotics are minimized.

Arun Mullaji [7] in 2009 reviewed the effectiveness of a mixture of opiod, corticosteroid and a local anaesthetic for periarticular injections in patients undergoing bilateral TKR. They injected one of the two knees with the anaesthetic cocktail. They reported significantly lower pain scores and better quadriceps recovery on the side that had the periarticular injection of the anesthetic cocktail, as compared to the side that did not have the injection.

Thorsell M et al [8] in his comparative study on total knee arthroplasty patients using local infiltration anesthesia technique with ropivacaine, ketorelac and adrenaline to epidural anesthesia reported earlier mobilization in the group treated with local infiltration technique. They concluded that this technique also offered better patient satisfaction and hence was better for postoperative pain relief than epidural anesthesia**.**

Spreng UJ et al [9] compared the efficacy of local infiltration anesthesia and epidural anaesthesia in total knee arthroplasty patients and reported that epidural anaesthesia provided better pain relief in the immediate postoperative period, where as local infiltration anaesthesia provided better pain relief after the initial 24 hours. Epidural

anaesthesia was associated with side effects as hypotension. Local infiltration group were mobilized faster, had showed better knee function and shortened hospital stay.

Sean VW et al [10] compared the effect of steroids in the periarticular infiltration solution and reported that the group which received the steroid reported lower pain scores, lesser morphine consumption and early discharge. Though there was better knee movement and better muscular strength in the steroid group in the early stages in the medium and long term evaluation the steroid group did not have any difference from the control group.

In 2012 Scott C E et al [11] evaluated the effect of local periarticular infiltration on the incidence of heterotopic ossification seen after hip replacement and also on the opiod requirement postoperatively. They reviewed 118 cases without periarticular infiltration and 211 with periarticular infiltration. They inferred that heterotopic ossification was not reduced by the use of periarticular infiltrations, but they reduced the usage of opiods and reduced the length of hospital stay.

Yuenyongviwat V et al [12] in 2012 evaluated the efficacy of bupivaccaine alone when used for periarticular injections for pain control in patients undergoing total knee arthoplasty and reported that it provided effective pain control, lesser complications and reduced consumption of morphine.

Nattapol Tammachote et al [13] compared the pain control effect of intrathecal morphine and multimodal drug injections in patients undergoing total knee arthroplasty. They found that though initially there was no difference between the two modalities, 12 – 16 hrs postoperatively the intrathecal group consumed significantly more ketorelac and that the side effects of nausea and vomiting was also more in this group compared to the group treated with multimodal drug injections.

In contrast to this in 2012 Crowley et al [14] reviewing 843 patients concluded that the studies that compared femoral nerve blocks to placebo or epidural injections failed to show any reduction in the length of hospital stay.

A similar report was provided by Gibbs et al [15] where he reported that though the local anaesthetic infiltrations were associated with more pain control there was no evidence that this modality of treatment reduced the hospital stay.

Wylde et al [16] in 2011 in his study to develop a protocol to determine the effect of local infiltration of a local anaesthetic to reduce postoperative pain in osteoarthritis patients undergoing total hip replacement and total knee replacement surgeries suggested that the chronic pain experienced by the patient post operatively may be related to acute post operative pain. He also suggested that if the chronic pain continues, the surgical treatment would have failed to attain its primary objective – that is relief from pain for which the patient has indeed undergone the treatment.

Other drugs used in the cocktail:

Noradrenaline:

Nor adrenaline is a catecholamine normally produced in the body by adrenal medullary cells. It acts as both hormone and neuro transmitter. It has the effect of vasoconstriction by increasing the peripheral resistance. In this cocktail the main function of noradrenaline is to cause local vasoconstriction so that the other drugs are retained at the site for a longer period of time, there by prolonging the effective anaesthetic action.

Depomedrol:

Depomedrol is an anti-inflammatory glucocorticoid for intramuscular, soft tissue, intra-articular, or intralesional injection. The suspension contains methyl prednisolone acetate, polyethylene glycol, polysorbate, monobasic sodium phosphate, dibasic sodium phosphate and benzyl alcohol. The action is primarily anti inflammatory. Secondarily it alters the immune response of the body to various stimuli. Depo-Medrol has been used as adjunctive therapy in acute gouty arthritis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, acute and subacute bursitis and synovitis of osteoarthritis. In this cocktail we aim to utilize the anti-inflammatory effect of the drug thereby reducing the post operative morbidity.

Morphine:

This is derived from opium and is an analgesic drug acting on the central nervous system. Morphine is considered the gold standard in relieving intense pain. When administered by a parenteral route it gives a duration of action of about 3-4 hours.Side effects include constipation, addiction, tolerance and withdrawal.

Morphine acts on the myenteric plexus of intestine, inhibits gastric emptying and reduces propulsive peristalsis of the intestine. Along with this reduction of gut secretion and increase in intestinal fluid absorption leads to constipation.

Morphine has been said to cause psychological, physical addiction. Development of tolerance also has been noted.

Ketorolac:

This is a commonly used analgesic classified under NSAIDS and is a heterocyclic acetic acid derivative. It acts by prevention of prostaglandin synthesis by competitive blocking of cyclooxygenase enzyme. This contributes to its analgesic, antipyretic and anti-inflammatory effects.

In higher doses for therapy extending the use of ketorolac has been associated with gastrointestinal bleeding. In some cases allergic reactions, and fluid retention edema also have been reported.

Cefazolin:

This is a first generation cephalosporin. It is a beta lactam antibiotic. The drug is usually administered by a parenteral route commonly intravenous or intra muscular. In addition to its use for combating infections it is also used prophylactically. For prophylactic use the drug is administered 60 minutes before the procedure and in procedures longer than 4 hours additional dose is given every 4 hours. Common dose is

2gms per dose for adults. Common spectrum against which cefazolin is effective include gram positive organisms, methiciliin susceptible Staphylococcus aureus and certain gram negative organisms as Escerichia coli and Klebsiella pnuemoniae. American academy of Orthopaedic surgeons recommend the use of cefazoline in orthopaedic surgeries. Total knee replacements are associated with high degree of deep wound infection. The infected prostheses are associated with large amounts of gram positive cocci. Hence the use of cefazolin in the analgesic cocktail might help prevent the deep wound infection.

Peri operative medications

Paracetamol - Metacin, Perfalgan:

Paracetamol or acetaminophen is commonly used as an antipyretic and analgesic agent. It has relatively lesser side effects than NSAIDs and acts as a central analgesic agent. Hepatotoxicity is the main side effect commonly reported with doses ranging from 1gm to 4 gm/day.

Major orthopaedic surgeries have used intravenous paracetamol for pain control and it is said to afford pain reduction in the initial 6 hours of the post operative period. In such cases consumption of morphine also was reduced during the first 24 hours after surgery.

NSAIDs:

The use of anti-inflammatory medications as part of a multimodal regimen has been advised strongly.

NSAIDs exert their antipyretic, analgesic and anti-inflammatory effects by reducing prostaglandin production in peripheral tissues. These agents inhibit the activity of COX enzymes. We have used aceclofenac in our study as a perioperative medication.

Aceclofenac is an analogue of diclofenac and commonly used for pain relief in rheumatoid arthritis and osteoarthritis.

Ondansetron – Emeset:

This is a serotonin receptor antagonist. It is indicated to prevent nausea and vomiting caused by surgery. It is well tolerated and has relatively less side effects. Commonly headache, constipation and dizziness are the reported side effects.

Omez – Omeprazole:

This is a proton pump inhibitor and prevents the final stage of acid production in the stomach. It is routinely used in the treatment of gastroesophageal reflux disease, peptic ulcer and erosive eosophagitis. Here this has a prophylactic action against the development of peptic ulcers secondary to the use of NSAIDs

Pregabalin:

This drug is a successor of gabapentin. Primarily it is an anticonvulsant drug usually used to control neuropathic pain. It has also been indicated in cases of fibromyalgia and in controlling anxiety disorders.

It is not seen to be very effective in controlling acute pain. Some clinical trials in which pregabalin was used did not report any effect on postsurgical pain, but the consumption of morphine was found to be less in these cases leading to lesser side effects of morphine.

Common side effects include dizziness and drowsiness. Less common side effects reported are diplopia, blurred vision, weight gain and ataxia.

Cremaffin:

Contains liquid paraffin and milk of magnesia and is a laxative. This might help to reduce the constipation produced due to the morphine in cases of TKR

Isabgul:

Isabgul is psyllium seed husk. These are indigestible. They are a source of natural dietary fibre. They help to regulate normal gastrointestinal transit and relieve constipation. They are available in dried powdered form which is consumed after mixing with water. They are also available as capsules.

Others:

Major orthopaedic surgeries like hip and knee replacement are associated with a high risk of deep vein thrombosis. This forms the most common cause of re admissions in this patient group. The natural history of deep vein thrombosis has shown that, in many this causes no symptoms. But in a few, ongoing stasis of venous system during the post

operative period emboli can expand, and break free leading to pulmonary embolism, often after the patient leaves the hospital.

Several measures are currently used prophylactic ally, including elastic stockings, intermittent pneumatic compression to reduce stasis, aspirin and various forms of anticoagulation to counteract hypercoagulability. Passive measures like elastic stockings have been in use for years and do help in preventing venous thrombo embolism. The rationale of elastic stockings usage and raising the foot end of the bed is the belief that if the venous stasis is minimized thrombosis is unlikely. Compared to this, intermittent pneumatic compression of the calf muscles has a much better preventive capability. Suppression of major stimulus for local thrombin development due to stasis is the aim of chemical thrombo prophylaxis. Aspirin as an inhibitor of thrombin generation is only modest, and in major surgeries associated with hypercoagulability aspirin alone is unlikely to be sufficiently protective. Over the years anticoagulants used against thromboprophylaxis include warfarin, heparin and low molecular weight heparin. It has shown that all these agents are equally effective in the prevention. The disadvantage of anticoagulation is its risk of bleeding. This price to pay to prevent thromboembolism seems acceptable since most of the bleeding associated with this is minor. Advantage of low molecular weight heparin compared to warfarin and heparin is, this does not need close monitoring. The duration of therapy according to the current guidelines is to extend the recommended prophylaxis for 10 days. This is in addition to the mechanical prophylaxis and aspirin which are given concomitantly. Aspirin tablets are usually continued for six weeks. Mechanical prophylaxis includes active dorsiflexion and plantar flexion movements of the ankle and passive mobilization of the ankle along with calf

massage. The above protocol is titrated according to the severity of the risk involved in the development of deep vein thrombosis. In our institution post operatively all patients undergoing total hip and knee replacements receive anticoagulant therapy according to the anti deep vein thrombosis prophylaxis protocol.

Anatomy of the knee joint:

The knee is a hinge type of synovial joint that has movements which are complex. The movements are flexion, extension and rotatory. The main bones associated with knee are the distal end of femur, the proximal end of tibia and the patella. The functional compartments of the knee joint include patellofemoral, medial and lateral tibiofemoral joints. These bones are bathed in the synovial fluid encompassed inside the synovial membrane called the capsule. The medial and lateral condyles of the femur articulate with the proximal tibial condyles to form the medial and lateral tibiofemoral joints respectively. The femoral condyles diverge posteriorly and distally with the lateral femoral condyle wider in the anterior aspect than the posterior aspect while in comparison with the medial condyle. It also presents with an intercondylar notch in the posterior aspect. The radius of the condyles in a sagittal plane reduces anteroposteriorly.

The tibial aspect of the joint consists of the medial and lateral tibial condyles separated by an intercondylar eminence composed of lateral and medial tubercles.

The patella is a sesamoid bone developing from the quadriceps tendon. The posterior aspect of patella has a medial and lateral articular surface which in turn

articulates with the condylar groove of the femur. At birth the patella is represented by a cartilage. This gets ossified by the age of 3 – 5 years.

In addition to the osseous components, the knee joint comprises of articular cartilage which covers the bony ends and disks or menisci. The articular cartilage is thin elastic tissues that protect the bone ends and prevent them from rubbing against each other. The knee joint has both hyaline and fibrous cartilage. The articular cartilage are mainly hyaline in nature where as the menisci are made up of fibrous cartilage. The cartilage has very low self regenerative capacity and hence is prone for degeneration. The hyaline cartilage on repeated stress undergo repair and is replaced by fibrous cartilage which is of less functional quality and has greater potential for degeneration.

Menisci are semilunar fibrocartilagenous structures seen inside the knee joint. At the centre of the knee joint these menisci are flattened. They are fused to the synovial membrane at the periphery. The menisci deepen the tibial sockets and thus disperse the forces that come into play at these bony ends by its concave shape and cartilaginous nature. This shock absorption nature of the menisci makes it more prone to traumatic injuries.

The other structures that stabilize the knee joint are the ligaments namely the medial and lateral collateral ligaments and the cruciate ligaments. They can be divided into extra capsular and intra capsular.

The intra articular structures include anterior and posterior cruciate ligaments. The anterior cruciate ligament extends from the lateral condyle of the femur to the anterior intercondylar area. The primary function of this ligament is to prevent the anterior translation of the tibia relative to the femur. The posterior cruciate ligament extends from the medial condyle of the femur to the posterior intercondylar area of the tibia. This prevents the posterior translation of the tibia relative to the femur. The transverse ligaments, meniscofemoral and meniscotibial ligaments are of lesser importance. The transverse ligament serves to attach the two menisci anteriorly. The anterior and posterior meniscofemoral ligaments extend from the posterior horn of the lateral meniscus to the medial femoral condyle. The meniscotibial ligaments or coronary structures extend from the inferior edges of the menisci to the periphery of tibia.

Extracapsular ligaments include the patellar ligament and the collaterals. The patellar ligament extends between the inferior pole of the patella and the tibial tubercle. The primary role of this ligament is to provide a mechanical leverage to the joint. The collaterals include the medial and lateral collateral ligaments. The medial collateral ligament stretches from the medial tibial condyle to the medial epicondyle of the femur. The main function of this ligament is to prevent valgus strain.The lateral collateral ligament stretches from the head of the fibula to the lateral femoral epicondyle. The primary role of this ligament is to prevent varus strain.

The movements permitted by the knee joint are mainly flexion and extension along the transverse axis. In the flexed position minimal medial and lateral rotation is also possible. The total range of motion is determined by the collateral ligaments and the musculature. In the extended position the stability of the joint is maintained by the

collateral ligaments and in the flexed position this is maintained by the cruciate ligaments.

Blood supply to knee arises from femoral (Descending genicular – articular and saphenous), popliteal (Superior medial genicular, middle genicular, inferior middle genicular, superior lateral and inferior lateral genicular), tibial (Anterior and posterior tibial recurrents) and anastomosis from descending branch of lateral circumflex femoral arteries.

The knee joint is innvervated by branches from obturator, femoral, tibial and common peroneal nerves. Other nerves associated with the knee joint include the saphenous nerve, the infra patellar branch of the saphenous nerve, the sural nerve,the medial sural cutaneous nerve and lateral sural cutaneous nerve, the superficial peroneal nerve as well as the deep peroneal nerve.

The obturator nerve arises from the anterior rami of the nerves L2 to L4. After dividing into anterior and posterior branches these supply cutaneous innervation to the medial aspect of the upper part of the leg and articular branches to the knee joint.

The femoral nerve arises from the anterior rami of nerves L2 to L4.Cutaneous branches of the femoral nerve include medial and intermedius cutaneous nerves as well as the saphenous nerve. Articular branches of the femoral nerve supply the hip and knee joints. The saphenous nerve is a branch of the femoral nerve. It supplies the skin on the medial side of the knee, leg and foot. The saphenous nerve also gives rise to the infra patellar branch, which pierces the sartorius muscle.

The nerve associated with the posterior compartment of the leg is the tibial nerve, a major branch of the sciatic nerve that descends into the posterior compartment from the popliteal fossa. It also gives rise to the medial sural nerve, which is a cutaneous nerve that supplies the middle of the back of the leg.

Common peroneal nerve originates proximal to the popliteal fossa and gives rise to the superficial and deep peroneal nerves. It also gives rise to the lateral sural nerve, which is a cutaneous nerve that supplies the lateral part of the back of the leg.

The lateral and medial sural nerves usually combine to form the sural nerve which is the cutaneous nerve of the back of the leg.

Assessment of Osteoarthritis

The pain, physical function and stiffness in patients suffering from osteoarthritis are assessed using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) using 24 parameters. This can be used to monitor the course of the disease or to determine the effectiveness of anti-rheumatic medications.

Pain:

(1) Walking

(2) Stair climbing

(3) Nocturnal

(4) Rest

(5) Weight bearing

Stiffness:

(1) Morning stiffness

(2) Stiffness occurring later in the day

Physical function:

(1) Descending stairs

(2) Ascending stairs

(3) Rising from sitting

(4) Standing

(5) Bending to floor

(6) Walking on flat

(7) Getting in or out of car

(8) Going shopping

(9) Putting on socks

(10) Rising from bed

(11) Taking off socks

(12) Lying in bed

(13) Sitting

(14) Sitting

(15) Getting on or off toilet

(16) Heavy domestic duties

(17) Light domestic duties

While the index was being developed performance of social functions and the status of emotional function were also included. These were not included in the final instrument.

Social function:

(1) Leisure activities

(2) Community events

(3) Church attendance

(4) With spouse

(5) With family

(6) With friends

(7) With others

Emotional function:

(1) Anxiety

(2) Irritability

(3) Frustration

(4) Depression

(5) Relaxation

(6) Insomnia

(7) Boredom

(8) Loneliness

(9) Stress

(10) Well-being

Scoring and interpretation is done according to the response. Points are given for each response and according to severity, if the response is slight or mild one point, two for moderate, three for severe and four for the extreme are given.

Knee society score:

Developed in 1989 the knee society considers all the existing rating systems and keeps the functional assessment and knee ratings separate. Only three parameters of pain, stability and range of motion are considered for knee assessment. Flexion contracture, extension lag and malalignment are considered as deductions. For a well aligned knee without pain a 100 point score is obtained with a 125 degree motion and negligible instability anterioposteriorly and mediolaterally. Function considers walking distance and stair climbing with deductions for walking aids. A patient who can walk unlimited distance and go up and down the stairs normally is given a maximum functional score of 100.

In the original method the knees and functional score are separate and do not alter with an increase in the age or with the severity of their medical condition.

Patient category

A. Unilateral or bilateral (opposite knee successfully replaced)

B. Unilateral, other knee symptomatic

C. Multiple arthritis or medical infirmity

Objective Scoring

Pain Points

None	50
Mild or occasional	45
Stairs only	40
Walking & stairs	
Moderate	30
Occasional	20
Continual	10
Severe	0

Stability (maximum movement in any position)

Anteroposterior

<5 mm 10

5-10 mm 5

10 mm 0

Mediolateral

<5º 15

6º -9º 10

10º -14º 5

15º 0

Flexion contracture

5º -10º -2

10º -15º -5

16º -20º -10

>20º -15

Extension lag

<10º -5

10º -20º -10

>20º -15

Alignment

5º -10º	0
0º -4º	3 points each degree
11º -15º	3 points each degree

Range of motion

(5º = 1 point) 25

Functional Scoring

Walking

Unlimited	50
>10 blocks	40
5-10 blocks	30
<5 blocks	20
Housebound	10
Unable	0

Stairs

Normal up & down	50
Normal up, down with rail	40

Up & down with rail	30
Up with rail; unable down	15
Unable	0

Functional Deductions

Cane	-5
Two canes	-10
Crutches or walker	-20
Other	20

If total score is a minus number, the knee score is zero.

A modification of this was proposed by Insall in 1989. Even this was a physician assessed one and had no correlation between the physician assessed knee scores and patient derived satisfaction scores. Hence a new scoring system was developed and copyrighted in 2011 [17] which included objective physician derived component and subjective patient derived component that evaluates pain relief, functional abilities, satisfaction, and fulfillment of expectations.

The new knee society scoring system has five components

1. Patient Demographics

2. Objective Knee Score - completed by the surgeon.

3. Patient Expectations – completed by the patient

4. Patient Satisfaction Score – completed by the patient

5. Functional Knee Score– completed by the patient

Preoperatively patients supply demographic information, and complete questions relating to their symptoms (pain measures), knee function, satisfaction with their current functional activities, and expectations of the results of the TKA. The surgeon completes information on Charnley functional classification and objective information on the alignment, instability, and range of motion of the knee.

The purpose of the present study was to assess the efficacy of periarticular infiltration of an analgesic cocktail, in terms of effective pain control and early rehabilitation following TKR. This was done by comparing the efficacy and complications i.e.: outcome with the current method of postoperative pain control protocol at our institution i.e. epidural analgesia: epidural infusion of 0.1% Bupivacaine and 2mcg/cc Fentanyl @4-6ml/hour with periarticular injection for pain control and early ambulation.

MATERIALS AND METHODS

MATERIALS AND METHODS

Type of study: A randomized controlled trial.

Setting:

The study was conducted in the orthopaedic department at Christian Medical College, Vellore between October 2013 and September 2014.

Cases and controls were evaluated in the orthopaedic outpatient department and explained about the study in detail and were given an information sheet for clarifications. Informed valid consent was taken. Patients were then admitted and were posted for unilateral total knee arthroplasty.

Eligibility criteria:

Patients undergoing unilateral TKR.

Exclusion criteria:

Bilateral TKR

Elderly >80 years

Revision TKR

History of Arrhythmia/Cardiac complications

Those not willing to give consent.

Sample size calculation

Non-inferiority-Two Group- Parallel – Two Means-Equal allocation		
Non-inferiority margin	-1	-1.5
Observed/Expected difference	0	0
Standard deviation	1.5	1.5
Effect size	0.67	1
Power (1- beta) %	80	80
Alpha error (%)	5	5
Required sample for the group I	28	12
Required sample for the group II	28	12

Table 1: Sample size computation

The mean (sd) of the pain scale on a 10 point Likert scale, currently is about 4 (SD=1.5). Keeping the non-inferiority margin at 1.5 with alpha and beta errors at 5% and 20% respectively, the sample size needed was 12 subjects in each arm.

Method

New clinically diagnosed cases and controls were recruited for the study. Patients were explained about the study in detail and patient information sheet was given to the patient. Informed valid consent was obtained from patients who were willing to participate in the study. The proforma for the study was filled in the OPD and patient details were obtained. Patients operated in Orthopaedic unit II were included in the study. On admission the principle investigator collected the relevant demo graphic and clinical data using the predesigned proforma (appendix). History of diabetes mellitus and rheumatoid arthritis if any was taken. Parameters like walking distance, aids used, preoperative pain score (using the 11 point NPF (Numeric Pain Score) for pain), analgesics used etc was noted.

Visual analog score:

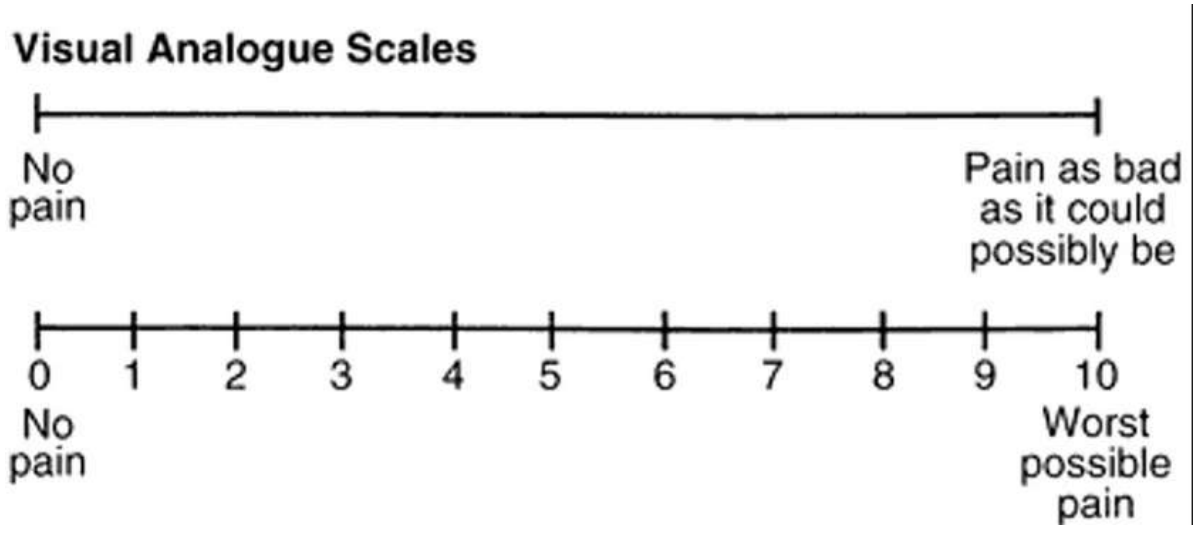


Figure 1: Visual analogue scale

Preoperative knee assessment was done using knee society score. Range of movement was measured preoperatively. Extensor lag if any was also noted. X-rays were reviewed and the deformity present documented.

The patients were randomized into two arms by block randomization.

In one arm, the patients received epidural analgesia for 48 hours post operatively.

In the other arm, the patients received periarticular injection of an anaesthetic cocktail of drugs.

Medications given in the peri operative period included

1. Tab.Aceclofenac 100milli gram bd(to be started 24 hours before surgery) – omit if creatinine >1.3 x 2 weeks
2. Tab.Omez 20 milli gram bd(to be started 24 hours before surgery) x 2 weeks
3. Post operaively:Inj Prefalgan 1gram Q6H IV x 48 hours followed by Tab.Metacin 1gram Q6H x 7days
4. Tab.Pregabalin 75 milli gram bd (to be started 24 hours before surgery) x 4 days post operatively
5. Inj Emeset 8 mg Q8H x 48 hours
6. Morphine 5milli gram s/c PRN – for increased pain - as judged by the patient upto Q4H

Other drugs included

- Anticoagulation as per protocol (Appendix)
- Cremaffin 2 tea spoon HS OD x 7 days
- Isabgul 2tea spoon HS OD x 7 days
- DMRADs from day 8

ORTHOPAEDIC OPERATING ROOM SETTING

All clinically diagnosed cases underwent a total knee replacement in our main operation theatre. Surgery was performed under GA (general anaesthesia)/spinal anaesthesia as per management plan by the anaesthesia staff using a standard medial parapatellar arthrotomy. A few relevant steps in the procedure are mentioned below:

Tranexamic acid 10-15milli gram /kilo gram – 3 doses was injected intravenously for control of blood loss starting approximately 15 minutes before tourniquet release. Two further doses at 3 hour interval were also given subsequently. This was used for all patients in this study.

A tourniquet was used for all patients, and it was set to a pressure between 300 milli meter of Hg (Mercury)and 350 milli meter of Hg depending on the patients BP (Blood Pressure) (With pressure equal to the systolic blood pressure of each patient plus 150 mm Hg) before skin incision and deflated before wound closure.

The implant used included Posterior stabilised and Cruciate retaining knees, from 2 companies – Genesis II (Smith & Nephew, Memphis, TN, USA) and PFC Sigma (DePuy,

Johnson & Johnson, Warsaw, IN, USA). The patella was replaced if a Posterior stabilised knee was used or if the patella was very badly eroded.

A closed suction drain was placed in the knee joint before wound closure and removed 48 hours after wound closure.

Postoperative blood loss in the drains was noted.

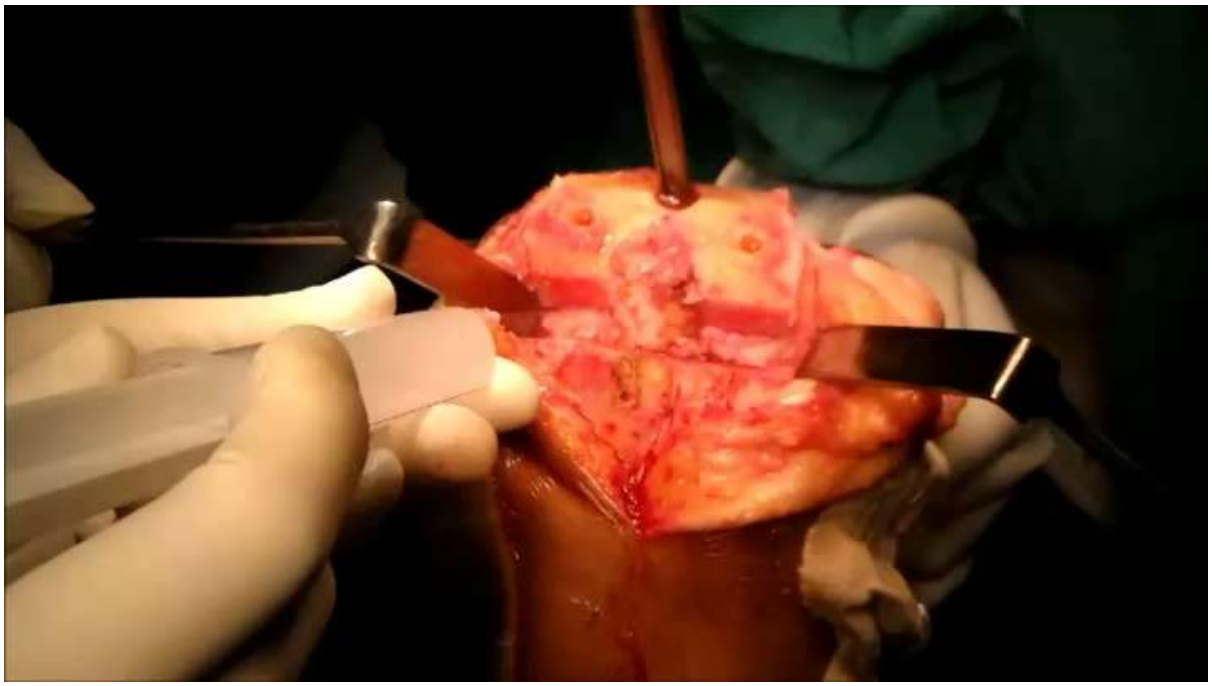
As mentioned before, randomization using opaque envelope (Phase 3 study) into either arm was done preoperatively by the principle investigator, and the anaesthetist was informed about the proposed method of postoperative pain control prior to the surgery.

The Peri-capsular Cocktail of anaesthetic drugs used for pain control include

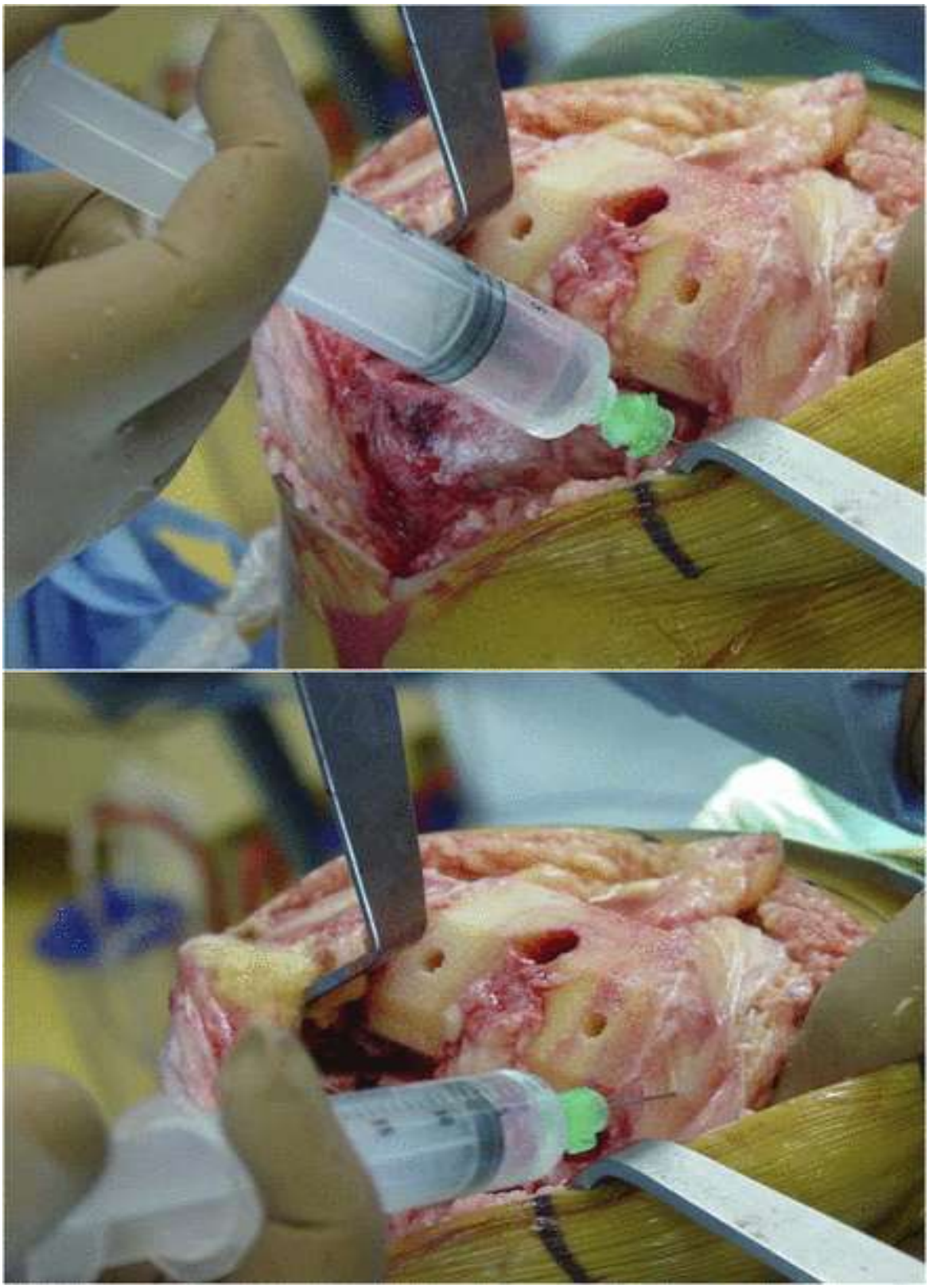
- 50ml 0.2% Ropivacaine
- 10 ml Saline
- 0.3 ml Noradrenaline (0.6mg)
- 40mg Depamedrol (Methyl prednisolone acetate)
- 10mg Morphine
- 30 mg Ketorelac
- 1 gm Cefazolin

The first 30 ml of the cocktail mixture was injected into the posterior knee capsule and soft tissue around the medial and lateral collateral ligaments before implantation of the actual components.

The quadriceps muscle, retinacular tissues, pes anserinus, and suprapatellar and infrapatellar fat pat were then infiltrated with the rest of the cocktail while the cement was setting.

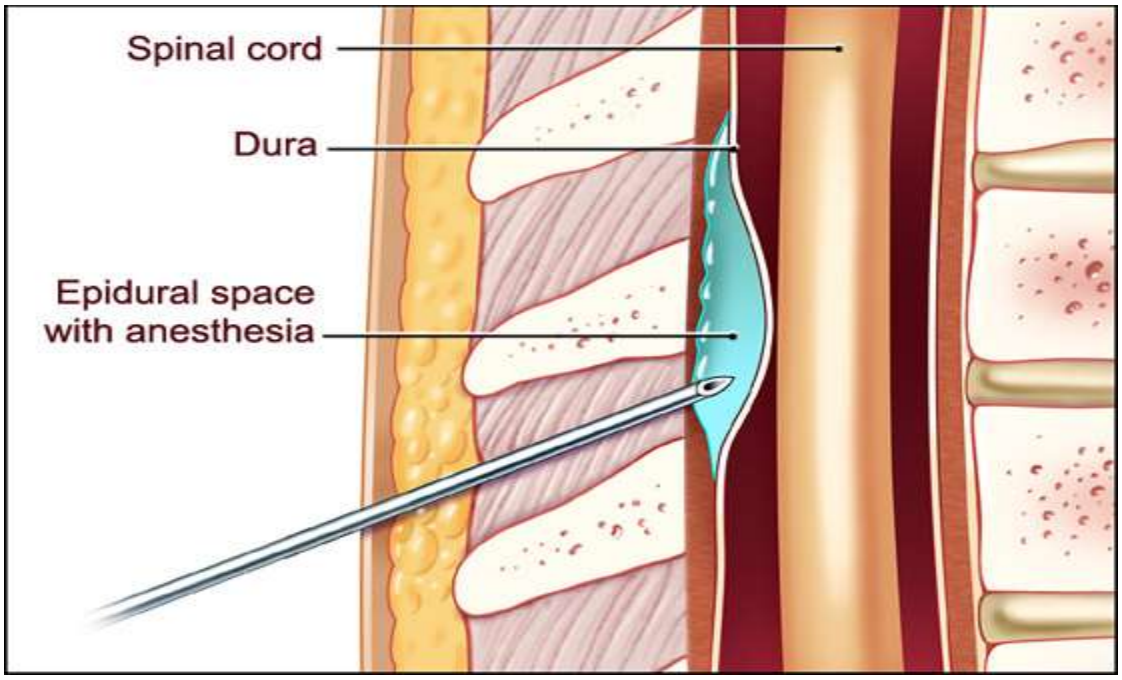


Pictures 1-3: Pictures showing the analgesic cocktail mixture being injected 1: Posteromedial strucures 2: Posterior capsule 3: Periosteum and gutters (Before implantation of the actual components)



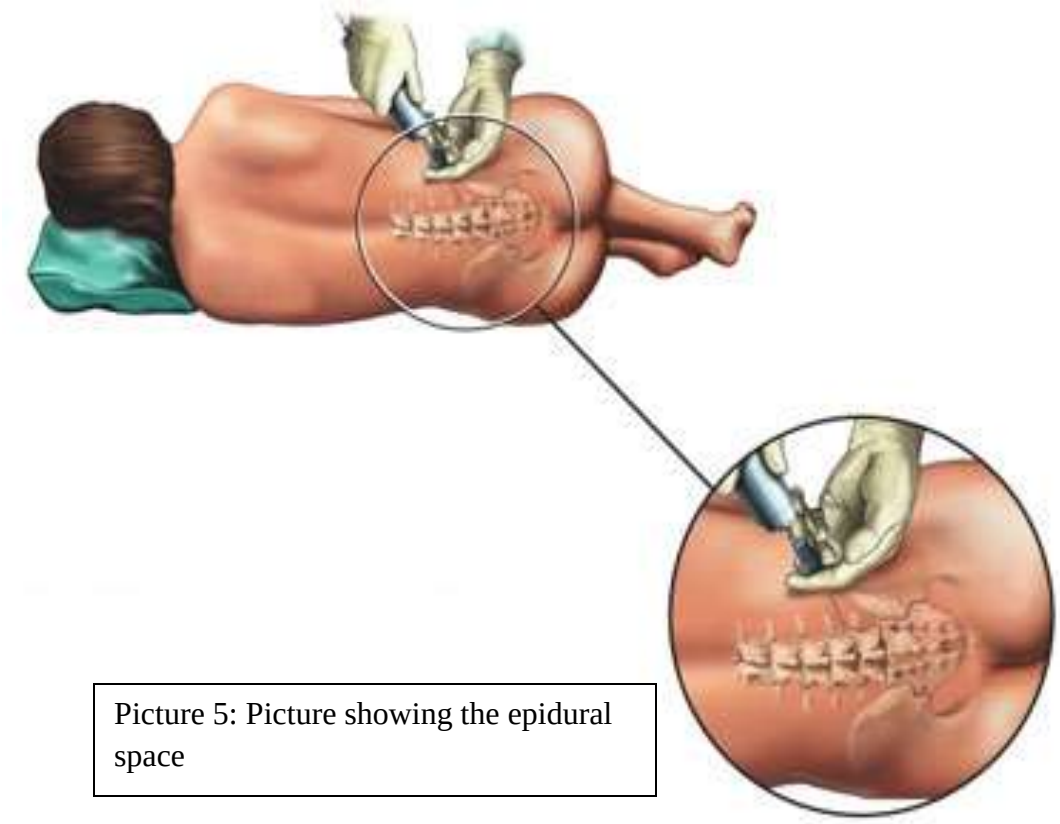
Reproduced from: J Bone Joint Surg Am,2011 Oct 19;93(20):1938-1943.

The 2nd arm received analgesia via an epidural line. The epidural infusion was given using an infusion pump with 0.1%Bupivacaine mixed with 2mcg/cc of Fentanyl given @4-6ml per hour for the first 48 hours post operatively. The dosage was increase if pain was not controlled. The increase in flow rate was noted, as was any bolus injections for additional pain control.



Picture 4: Picture showing the epidural space with anaesthetic drug

Reproduced from: http:// www.tsvs.net/js/blog/376/epidural-anesthesia-and-analgesia



Picture 5: Picture showing the epidural space

Reproduced from: http://withbabysolutions.com/epidural-anesthesia-childbirth/

Post operatively data regarding surgical date, side operated, anaesthesia used, components used, patella resurfacing done or not, type of knee whether posterior stabilized or cruciate retaining and the type of post operative analgesia (Epidural or analgesic cocktail) were documented.

Pain experienced by the patient using the NPS for pain was assessed postoperatively by the primary investigator on a daily basis. The pain score was determined every 4 hours by the nurses, and the patient was also reviewed by the principle investigator on a frequent basis. The highest NPS score for the day was noted, and recorded. The pain scores were noted on day 1-3, and again on day 10 prior to discharge.

Dosage of epidural infusion given in the post operative period was noted as well as any changes in the **flow rates** and any extra **morphine/epidural bolus** for breakthrough pain relief if any were also documented. For those who got pericapsular injections, the extra boluses of morphine were noted- for breakthrough pain.

Post operative physiotherapy schedule –

All patients were encouraged to perform foot pump exercises in bed and encouraged to do SLR (Straight leg raise) from the day 1 of the surgery – initially with a brace, and subsequently without.

Days to do active SLR with the brace in the supine position and lag on supine i.e.: SLR **without the brace** was documented. On the second day, they were encouraged to sit with the legs out of the bed, and do active quadriceps strengthening.

Amount of knee flexion possible and the lag on extension while sitting from the second post operative day were also documented.

Later all were encouraged to walk with a walker after the drain was removed. A brace for the knee was used till the patient could do an active SLR. They were started on active and passive range of movement exercises by sitting at bedside.

Number of days taken to **walk 50 meters without brace** and to climb a **flight of 14 steps** was documented.

All patients were discharged when they met the discharge criteria, which include being able to get in and out of bed independently, independently ambulate with a walker for 100 meters, and climb 20 steps.

The distance walked in **6 minutes with a walker** was recorded on the 10^{th} post op day.

Peri operative complications if any were also documented.

Adverse Events: Definitions

Nausea and vomiting:

Mild: Vomiting sensation with minimal retching.

Moderate: Significant retching + Vomiting- 1 episode.

Severe: More than 1 episode of vomiting.

Pruritis:

Mild: Minimal itching sensation

Moderate: Moderate Itching sensation - enough to disturb the patient -

not requiring medications

Severe: Itching sensation requiring medications

Urinary retention:

Mild: Feeling of abdominal fullness not requiring any treatment modalities like cold packs.

Moderate: Feeling of abdominal fullness with discomfort requiring other treatment modalities like cold pack to enable voiding.

Severe: Retention requiring catheterization.

Summary of Outcome measurement

i. Primary Outcome:

i. Pain - as estimated by the patients using a NPS till 72 hours post-operatively. The NPS for pain ranges from 0 (indicating no pain) to 10 (indicating extreme pain). Patients were advised to record the NPS every 4 hours and the highest pain score was noted for the first 3 days, and at the time of discharge.

ii. Function - Distance walked in 6 minutes on the 10^{th} post op day.

ii. Secondary Outcome/s:

i. The amount of Morphine s/c consumption until 48 hours after surgery

ii. Time taken to do a SLR with 5 degree lag; and 0 degree lag while supine

iii. Time taken to be able to climb up a flight of 14 steps.

iv. Time taken to be able to walk 50 metres with walker (without knee brace).

v. Distance walked in 6 minutes on the 10^{th} post op day.

Other parameters:

vi. Morphine-related side effects: Morphine-related side effects consisted of the incidence of nausea, vomiting, pruritis, urinary retention, and respiratory depression.

vii. Blood loss collected in closed suction drainage.

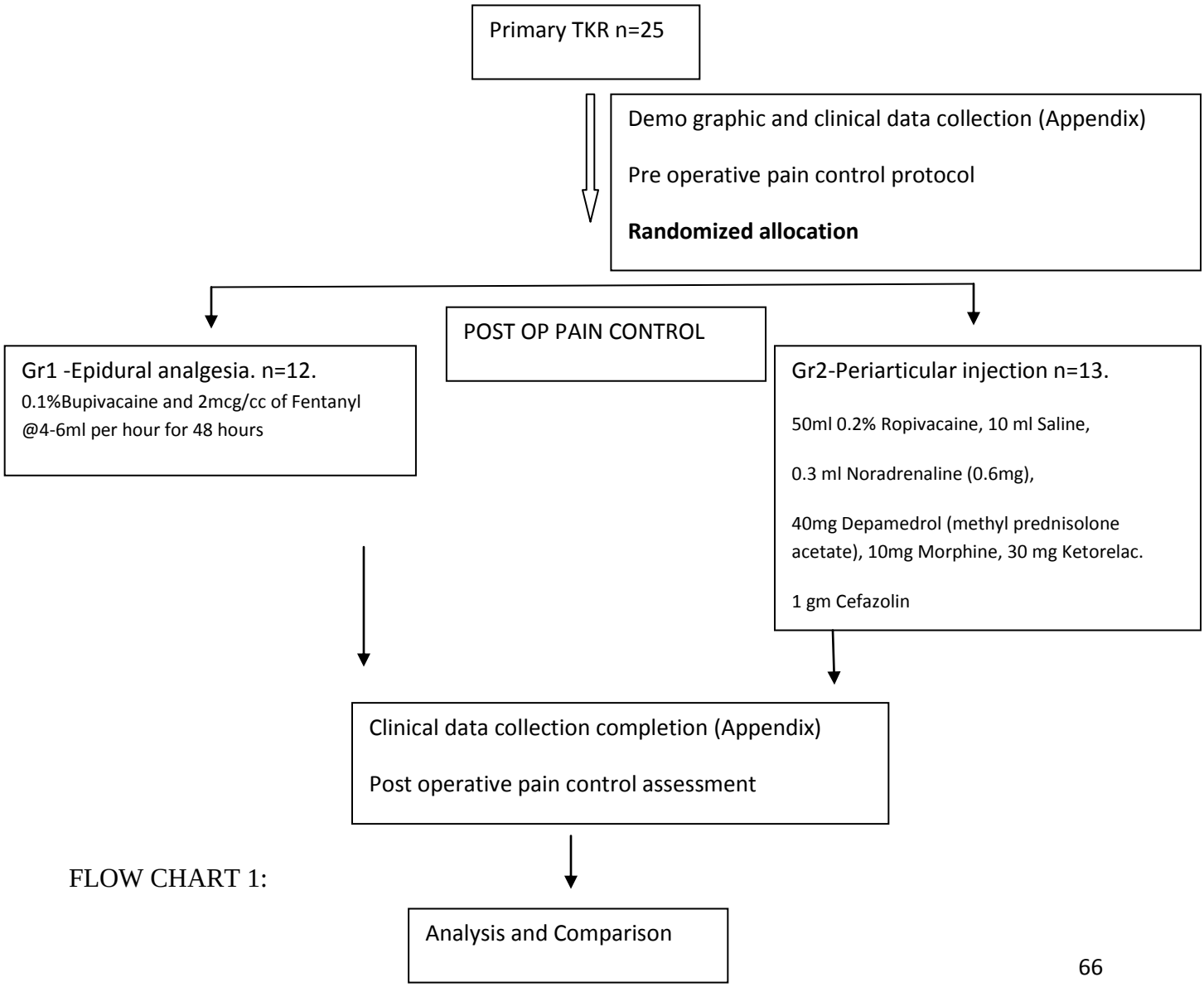
viii. Range of movement at Day 10.

Statistical Analysis

The data were analyzed using a repeated-measure ANOVA to compare the amount of morphine consumption, NPS for pain, range of movement and post operative functional rehabilitation capability.

Protocol Synopsis

Project Organizational Chart, Personnel

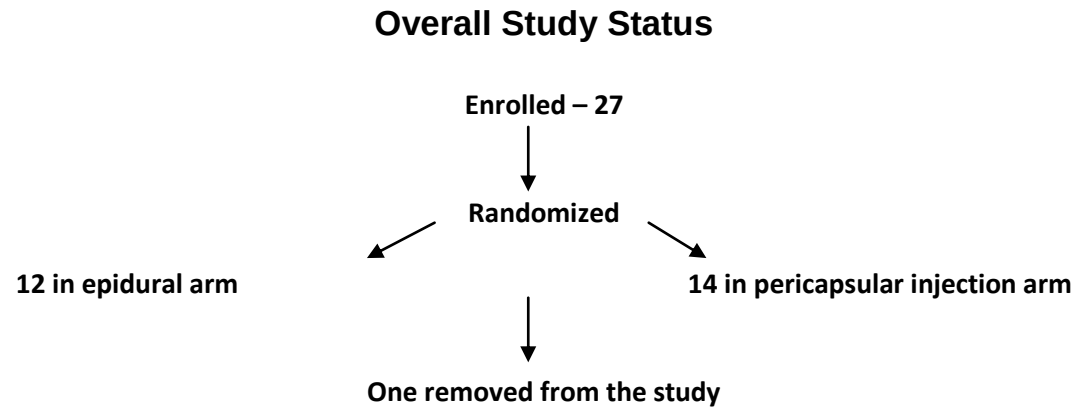


FLOW CHART 1:

RESULTS & ANALYSIS

RESULTS & ANALYSIS

A total of 27 patients were included in the study. One of the patients was excluded due to protocol deviation (The epidural pump was not available in the ward hence pain was controlled with Inj. Morphine given sub-cutaneously).



FLOW CHART 2

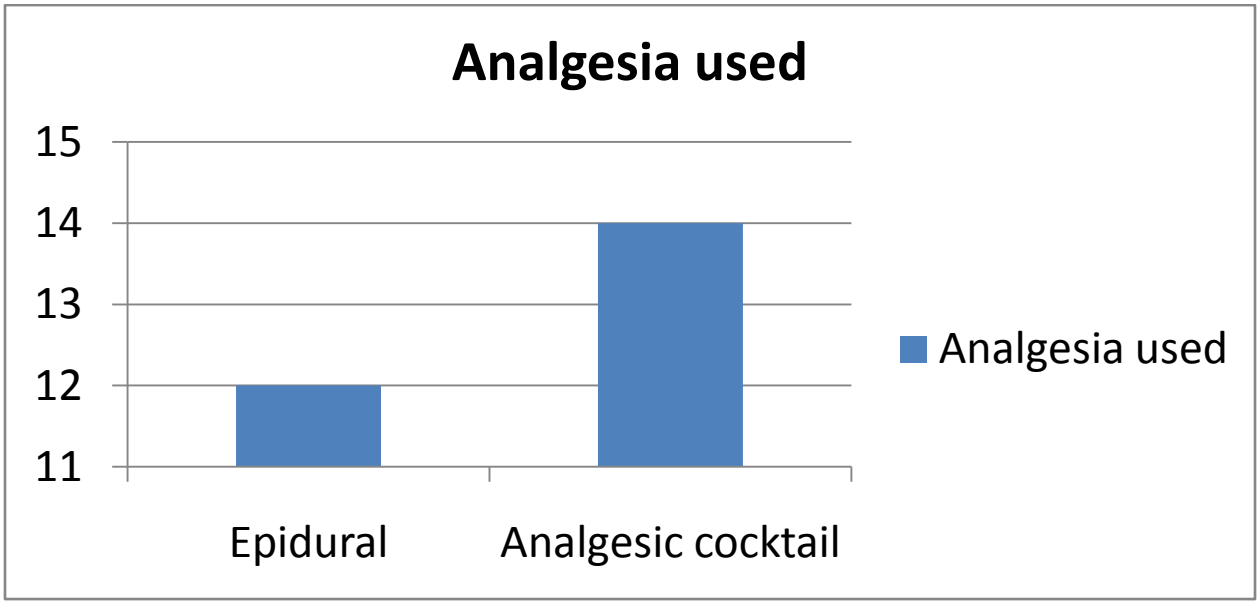


Figure 2: Bar diagram showing the analgesia used

Diagnosis:

They comprised 21 osteoarthritis, four rheumatoid arthritis and one gouty arthritis (Figure 3). Osteo arthritis formed the major part of the control study group forming (81 % of the study). The other arthritis knees studied were rheumatoid and gouty arthritis. Of these knees 12 had epidural infiltration and 14 had analgesic cocktail (Figure 2). Those patients who received analgesic cocktail, all had osteoarthritic knees.

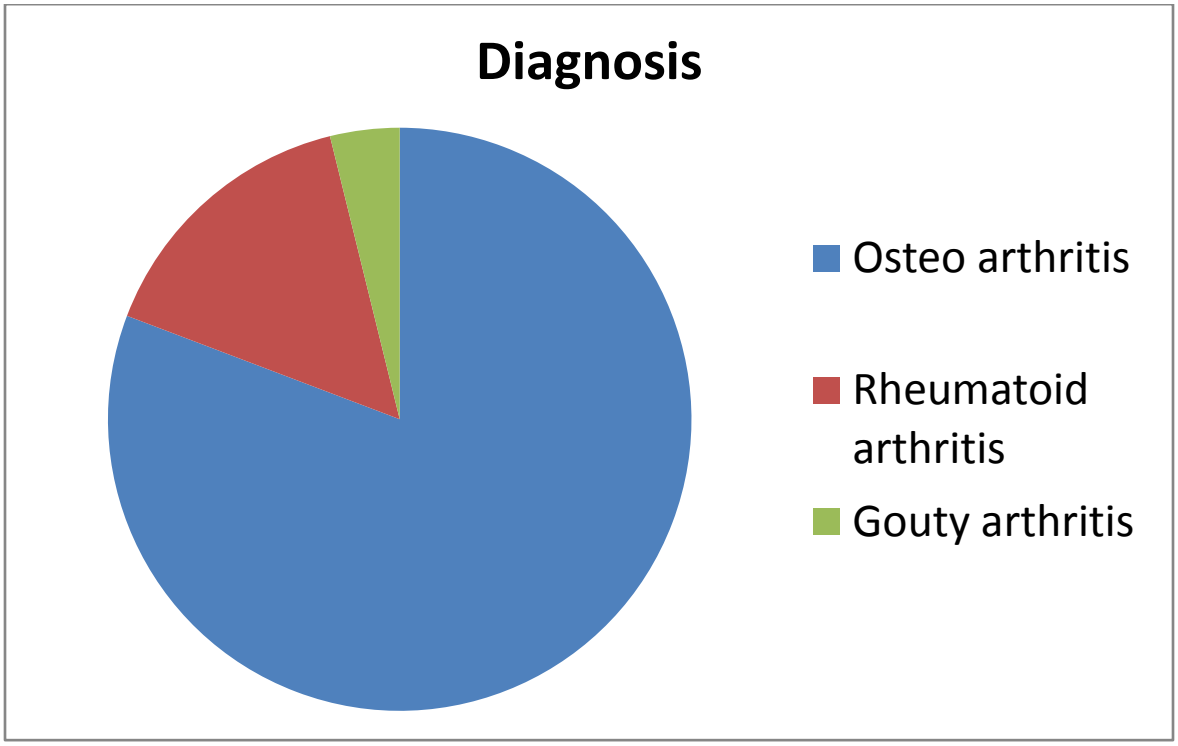


Figure 3: Pie diagram showing the various types of arthritis

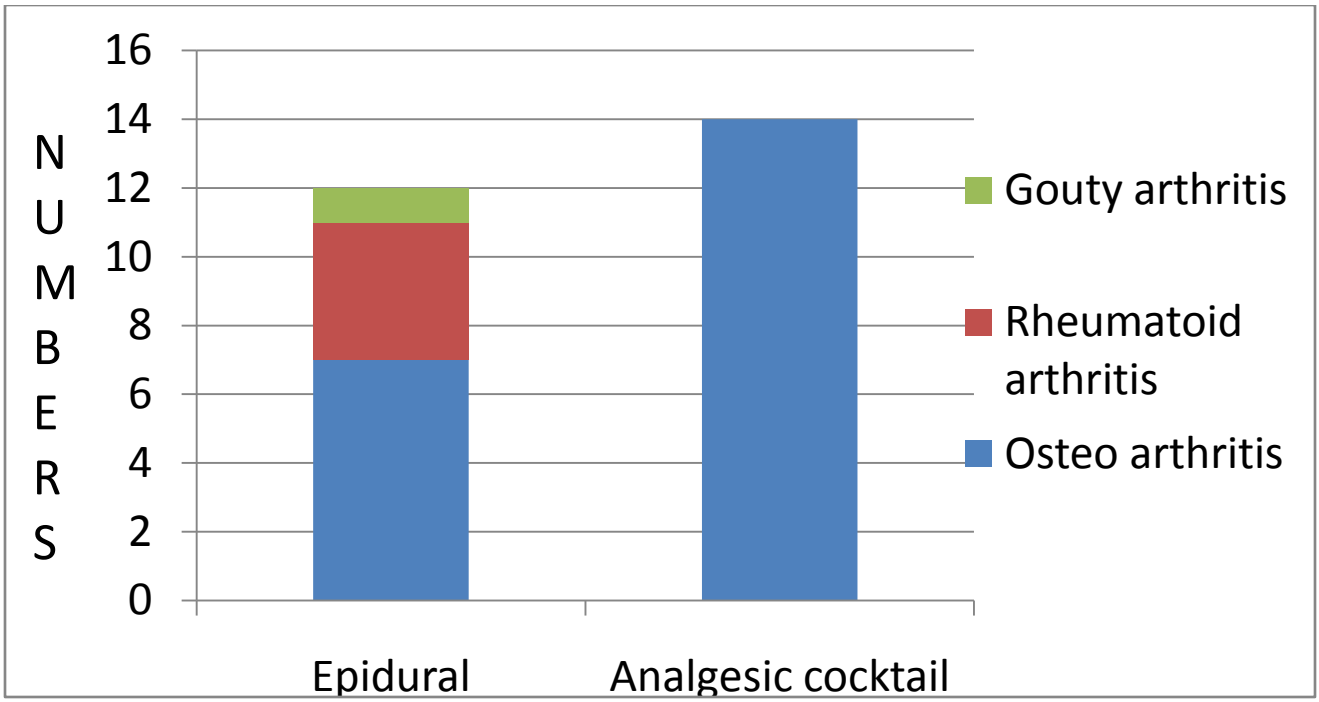


Figure 4: Bar diagram showing the number of arthritic knees and the type of analgesia given

Sex ratio of the control population:

There were 11 males and 15 females with females forming 58% of the study population (Figure 5). Of this five males and seven females had epidural and six males and eight females had peri capsular injection of the cocktail (Figure 6). Males comprised 42 % of the study population.

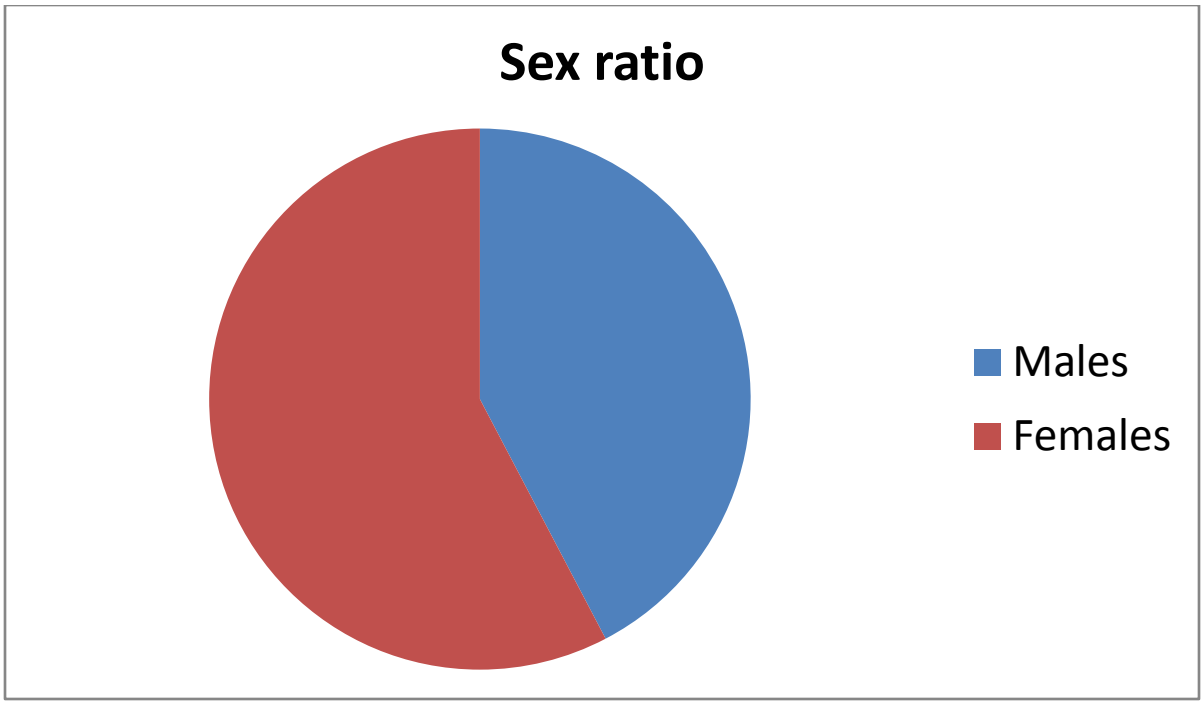
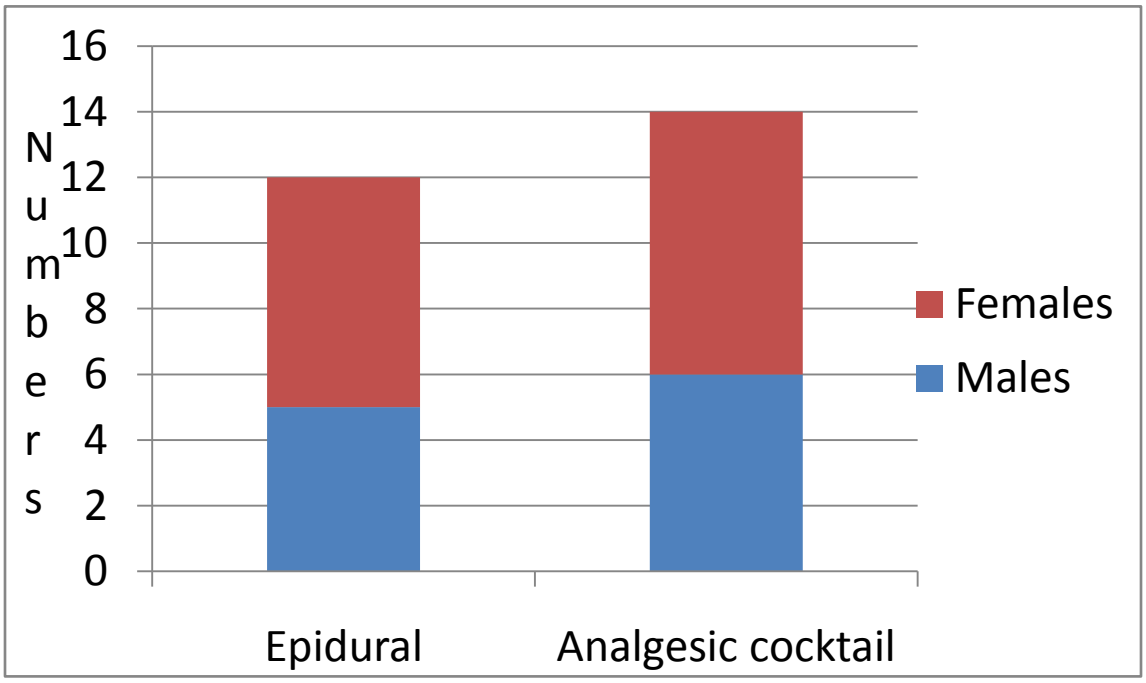


Figure 5 & 6: Pie and bar diagram showing the sex ratio and the type of analgesia given



Age distribution:

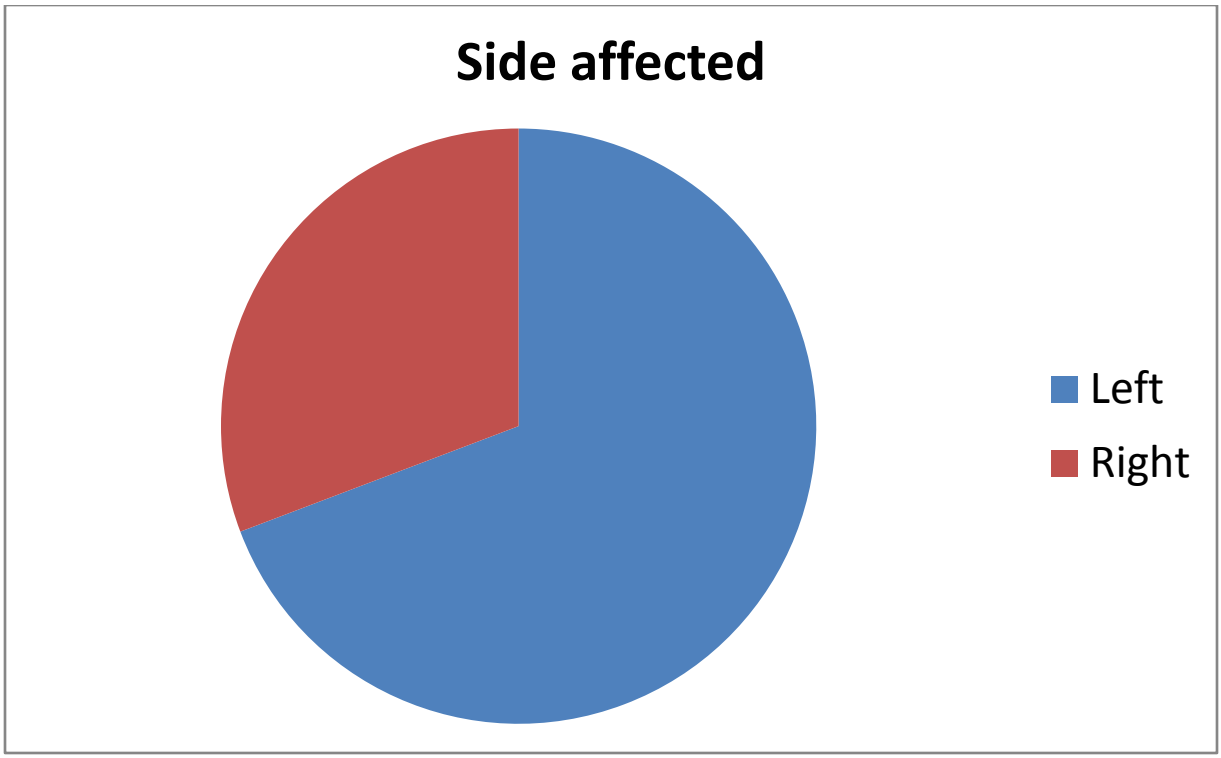
Middle aged people formed most of the study group. The mean age of the study population was 58 years. The mean age of those patients who received epidural infiltration was 56 years and that of the analgesic cocktail was 59 years. The lowest age group studied being 29 years and the oldest being 71 years.

Presenting complaints:

The chief presenting complaint of all the patients in the study group was pain and deformity though the duration was variable. Other symptoms were difficulty in doing activities of daily living, stiffness and locking. The duration of deformity and pain were variable.

Sides affected:

Left knees were seen more commonly affected than the right.18 knees of the 26 knees studied were left and the rest were right (Figure 7). Of the studied, eight left knees and four right knees were given epidural infiltration and ten left and four right knees had analgesic cocktail (Figure 8).



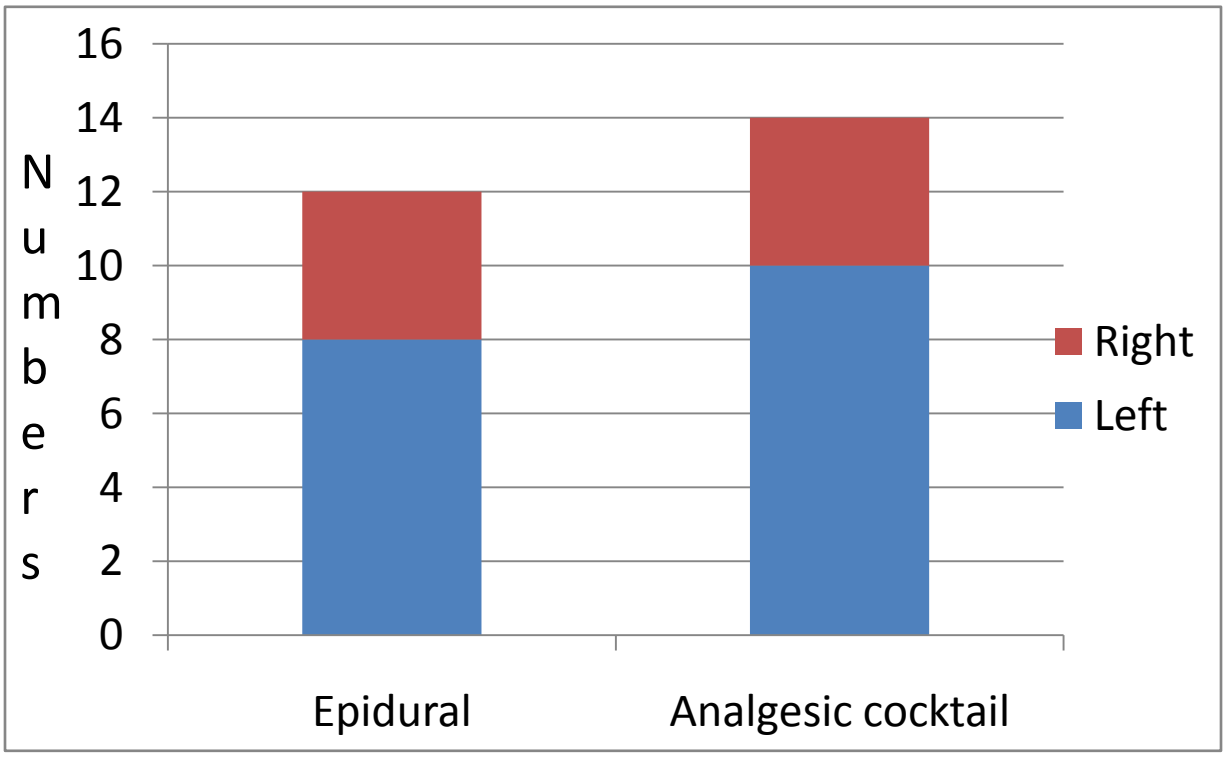


Figure 7 & 8: Pie diagram showing the number of each side and the bar diagram showing the type of analgesia given

Variables	Epidural (N=12)	Per capsular injection (N=14)	P Value
Age	56 ± 11.35	59 ± 8.64	0.327
Sex Male Female	 5 (42%) 7 (58%)	 6 (43%) 8 (57%)	 1.000
Side Right Left	 4 (33%) 8 (67%)	 4 (29%) 10 (71%)	 1.000
Diagnosis OA RA GOUT	 7 (58%) 4 (33%) 1 (9%)	 14 (100%) - -	 0.087
Pre operative functional score (KOSS) (0-100)	45.83 ± 32.46	59.29 ± 19.79	0.274

Table 2: Table depicting demographics

Co- morbidities: Diabetes:

The prevalence of diabetes in this study population was 34%.Nine out of 26 patients had diabetes. Five out of nine had epidural and the rest analgesic cocktail with no statistical significance (p value 0.683) (Figure 9).

Variables	Epidural	Per capsular injection	P Value
Diabetes Yes No	 5 (42%) 7 (58%)	 4 (29%) 10 (71%)	 0.683

Table 3: Table depicting percentage of diabetes

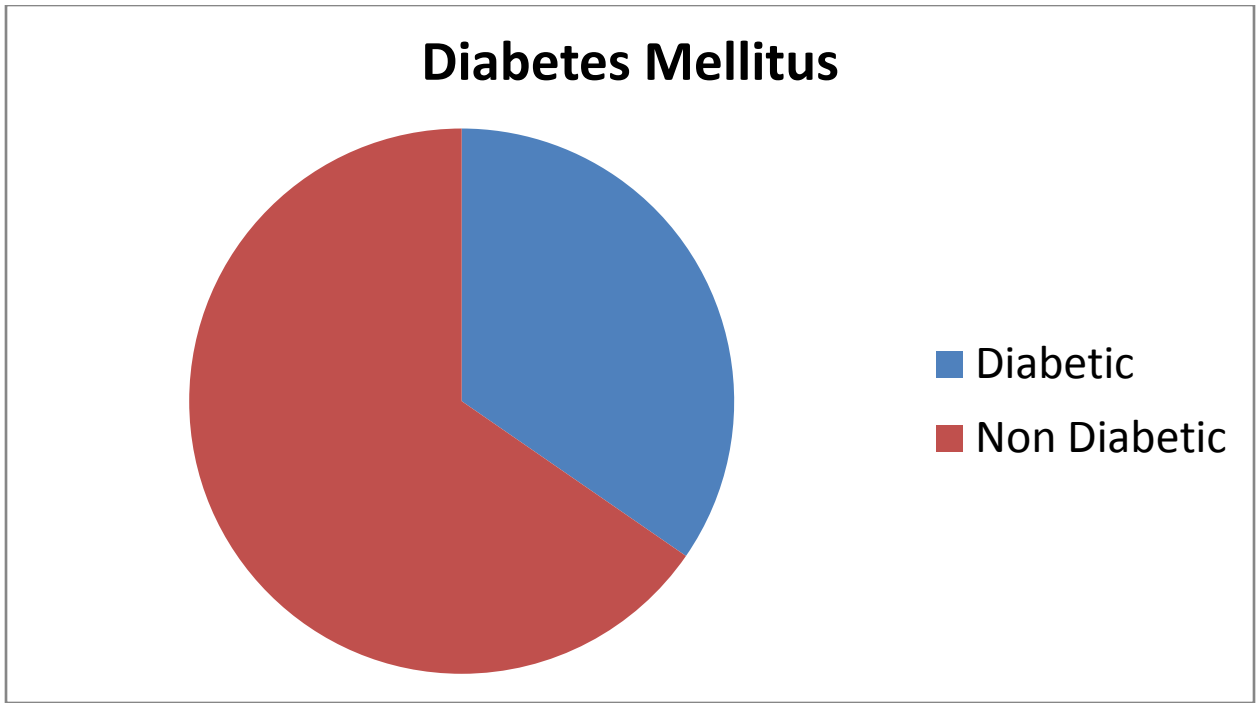


Figure 9: Pie diagrams showing the percentage of diabetic patients

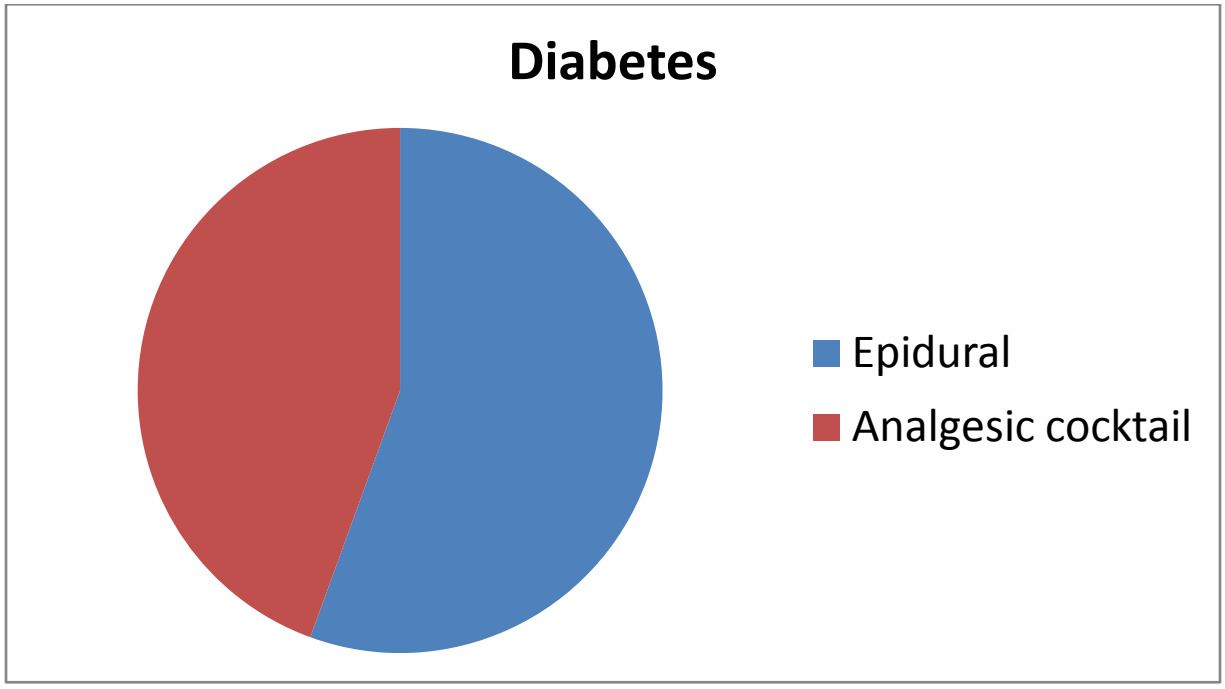


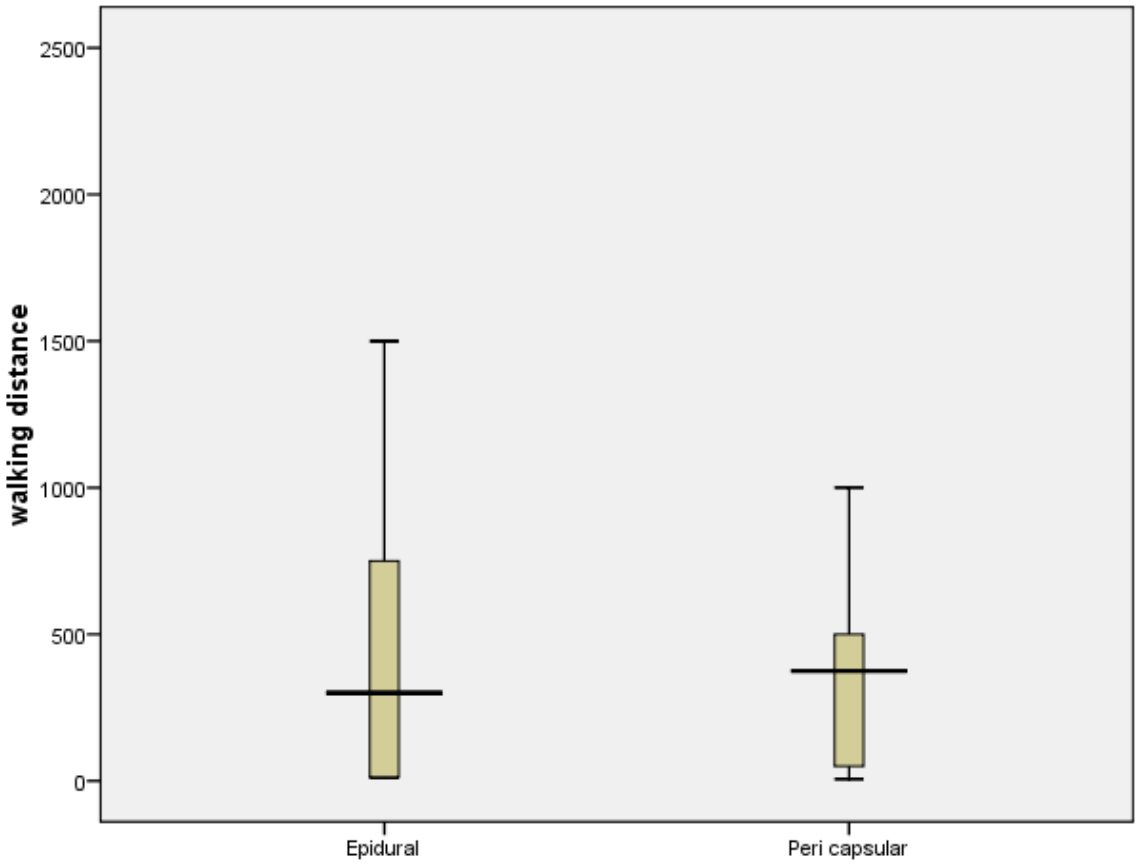
Figure 10: Pie diagrams showing the percentage of diabetes and the type of analgesia

Walking distance:

The mean walking distance of the study group before surgery was 609 meters in total. The mean walking distance for the epidural group was 413 meters and of the analgesic cocktail group 777 meters. Walking distance in comparison was much more affected among the epidural group than the cocktail group indicating a severe disease process but was not significant statistically (p= 0.649).

Variables	Epidural	Per capsular injection	P Value
Walking distance	450 ± 513	723 ± 1050	0.649

Table 4: Statistical analysis of walking distance



Graph 1: Graph showing difference in the walking distance between the groups

Aids used:

42 % of the study population used some kind of support for ambulation before surgery. Among the epidural group 50 % did not use any aid for walking. One of the patients was wheel chair bound and another used the support of two people while taking steps. The rest used a walking stick for support. Among the analgesic cocktail group nine out of 14 did not use any aid. The rest five used a walking stick (Figure 11). On analysis both the groups were equal on aid usage and there wasn't any statistical significance (p value 1.0).

Variables	Epidural	Per capsular injection	P Value
Aids used Yes No	 5 (42%) 7 (58%)	 5 (36%) 9 (64%)	 1.000

Table 5: Statistical analysis of aids

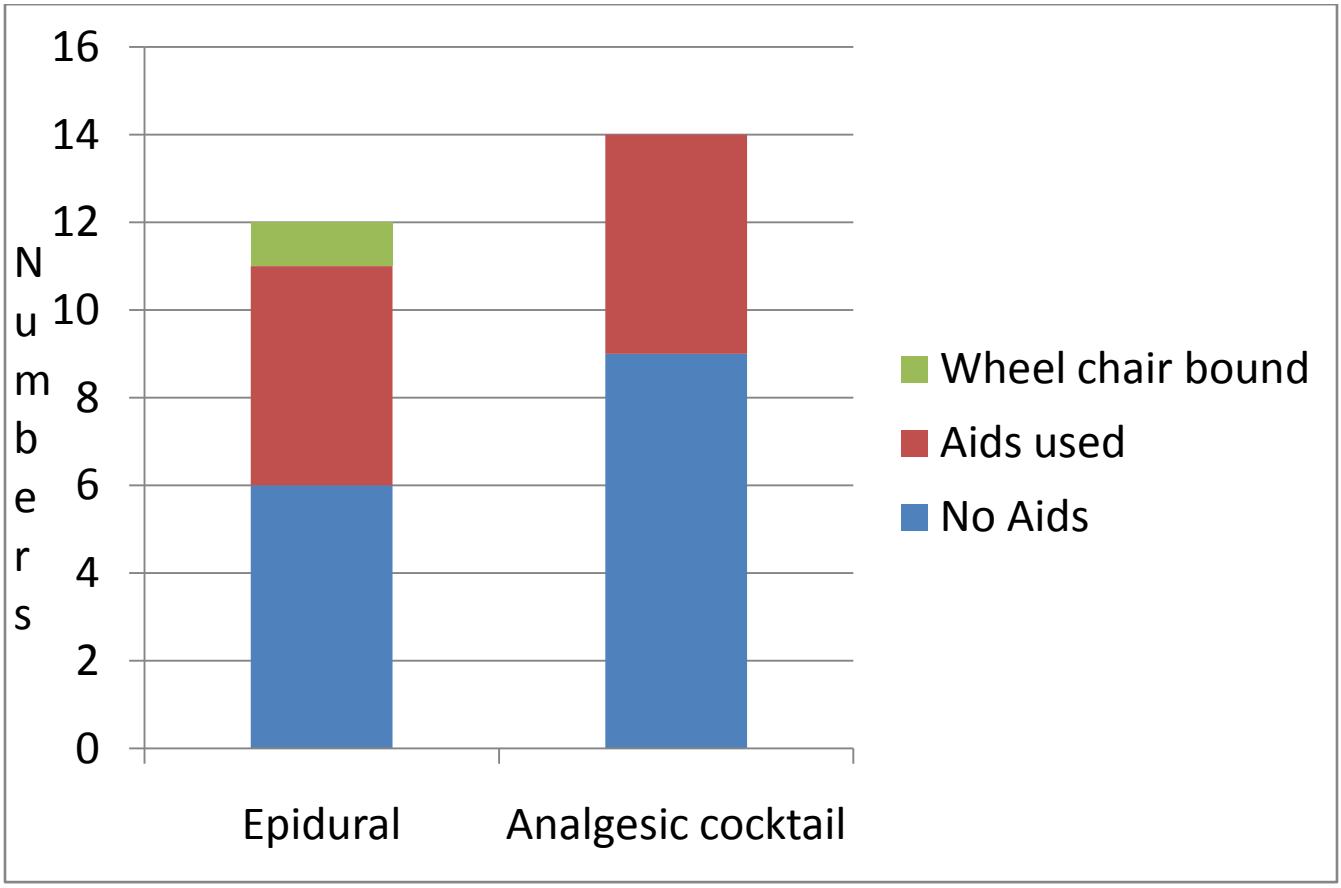


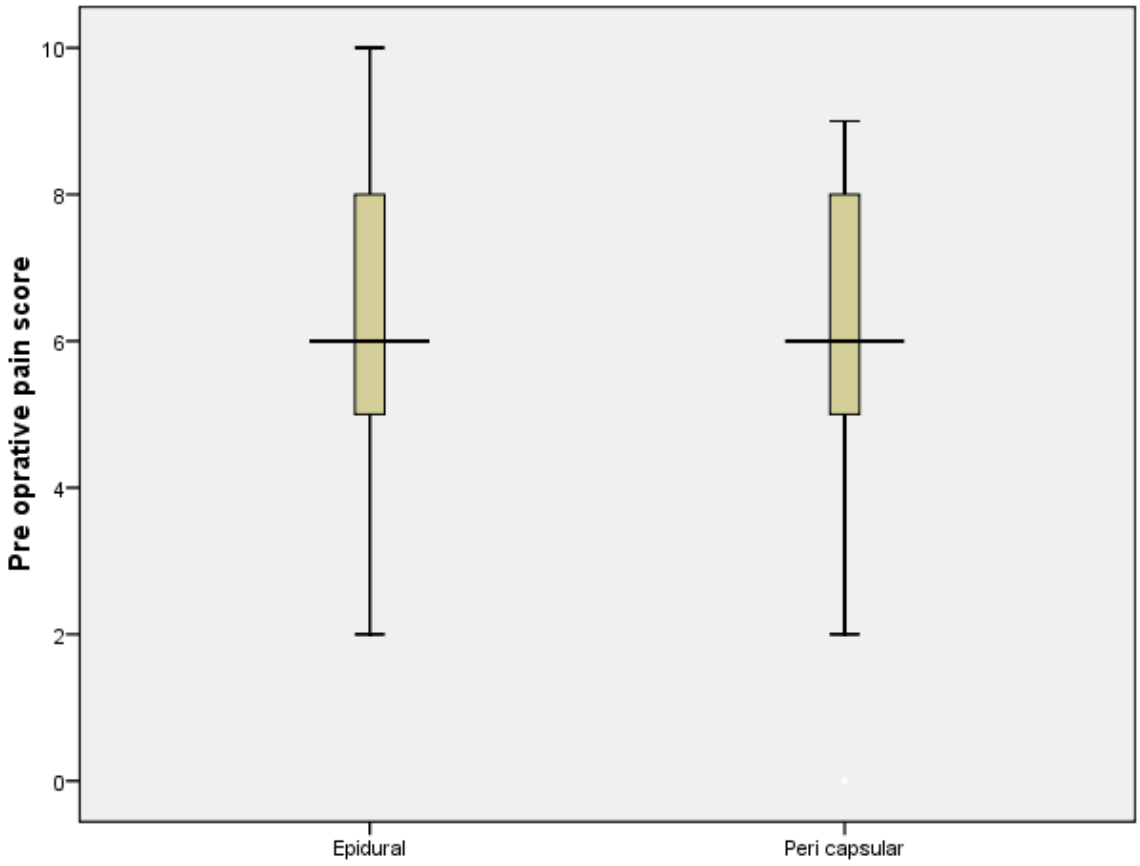
Figure 11: Bar diagram showing the distribution of aids used and the type of analgesia given

Pre operative pain score:

Average preoperative pain score of the epidural group was 6.25 compared to 5.4 in the analgesic cocktail. The maximum pain experienced by the epidural group was ten and of the analgesic cocktail was nine. The minimum pain score being two and zero. There was no significant statistical difference in the preoperative pain scores between the two groups on analysis (p value 0.494).

Variables	Epidural	Per capsular injection	P Value
Pre operative pain score	6.25±2.26	5.57±2.65	0.494

Table 6: Statistical analysis on pre operative pain score



Graph 2: Graph depicting the pre operative pain score

Analgesics used:

50% of epidural group used pain killers for pain control as a daily basis for activities of daily living while five out of 14 (36%) in the analgesic cocktail group. The rest 50% in the epidural and the 64% in the analgesic cocktail did not use any kind of analgesic medications for ambulation, even though few used pain killers as PRN basis for severe pain (Two out of 12 in epidural and four out of 14 in analgesic cocktail) (Figure 12). The difference in the usage of pain killers was not significant (p value 0.401).

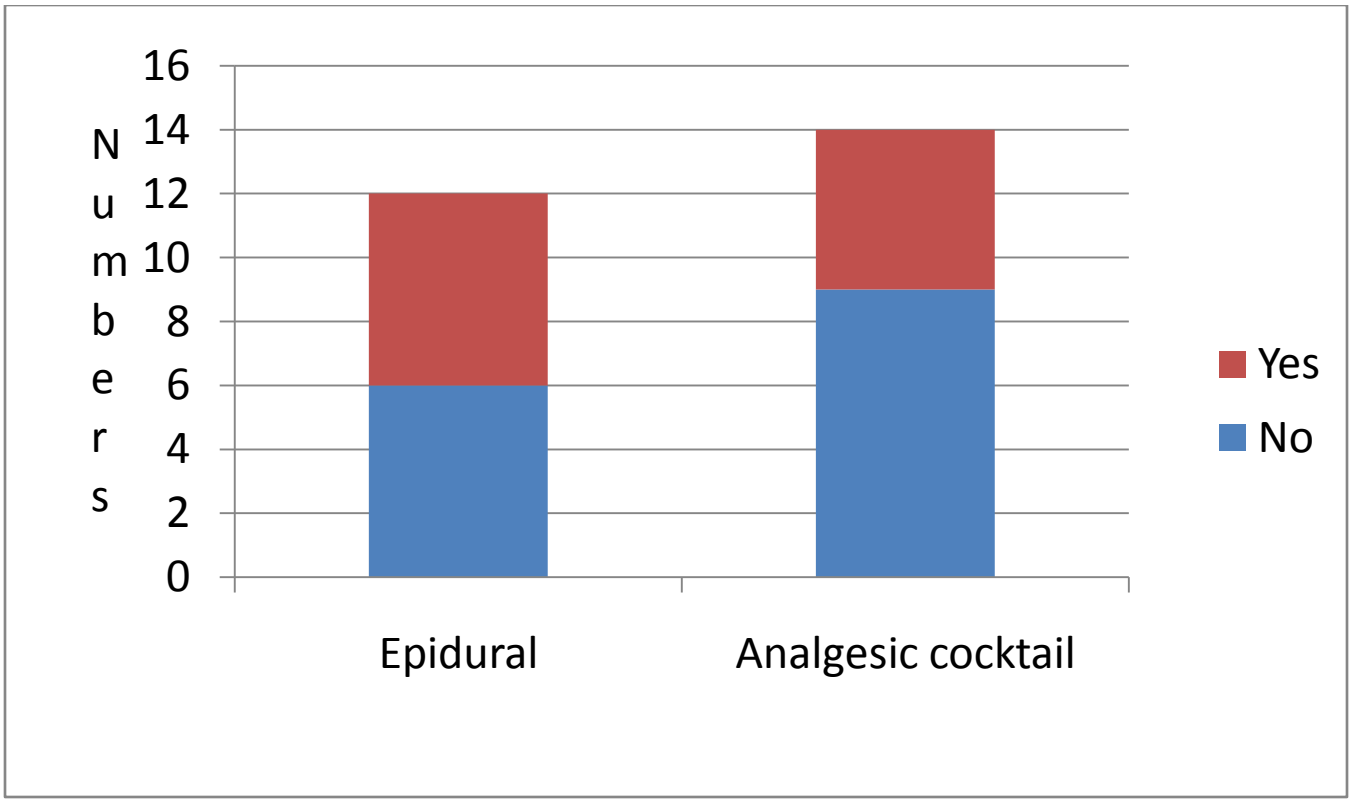


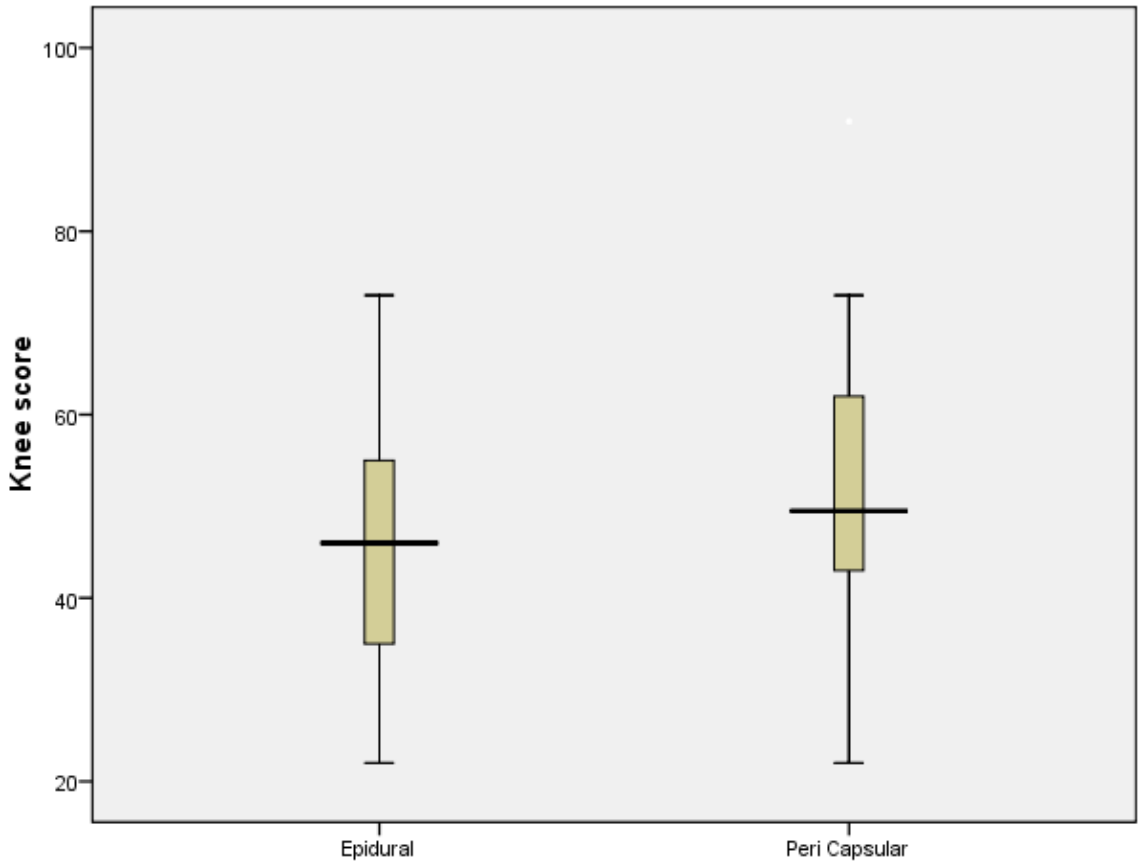
Figure 12: Bar diagram showing the number of patients using analgesics and the analgesia given

Knee society score:

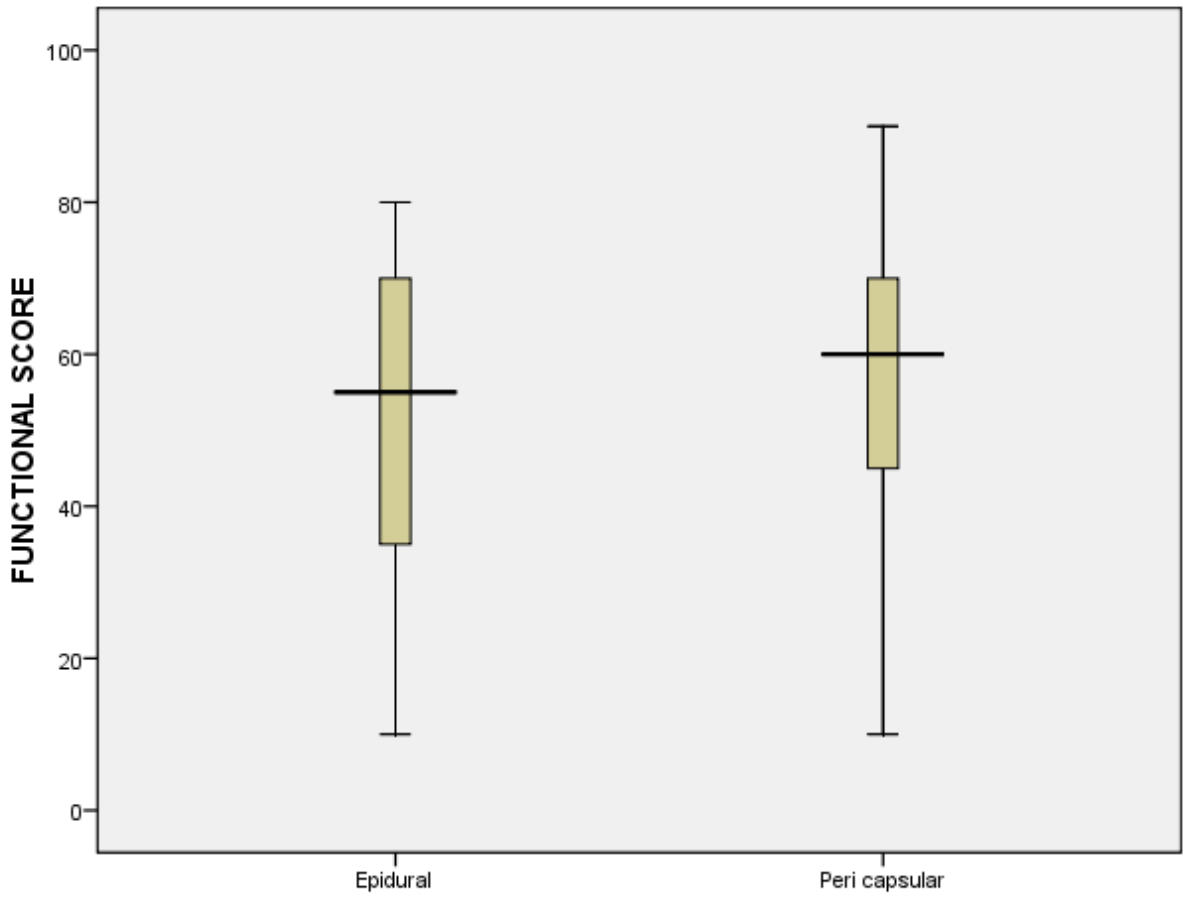
Knee society score has two components: Knee score and functional score. This was assessed for all the study subjects. The mean average score of the study subjects were 50.The score of the analgesic cocktail being higher than the epidural group. The analgesic cocktail had a score of 53 when compared to 46 for the epidural group. The mean average functional score was 53 for the whole study group. Both the scores were marginally better in the analgesic cocktail group but the difference was not statistically significant (p value 0.306).

Variables	Epidural	Per capsular injection	P Value
Knee society score	46±15.12	52.93 ± 18.14	0.306

Table 7: Table showing statistics on the knee society scores



Graph 3: Graph showing knee society score



Graph 4: Graph depicting functional score

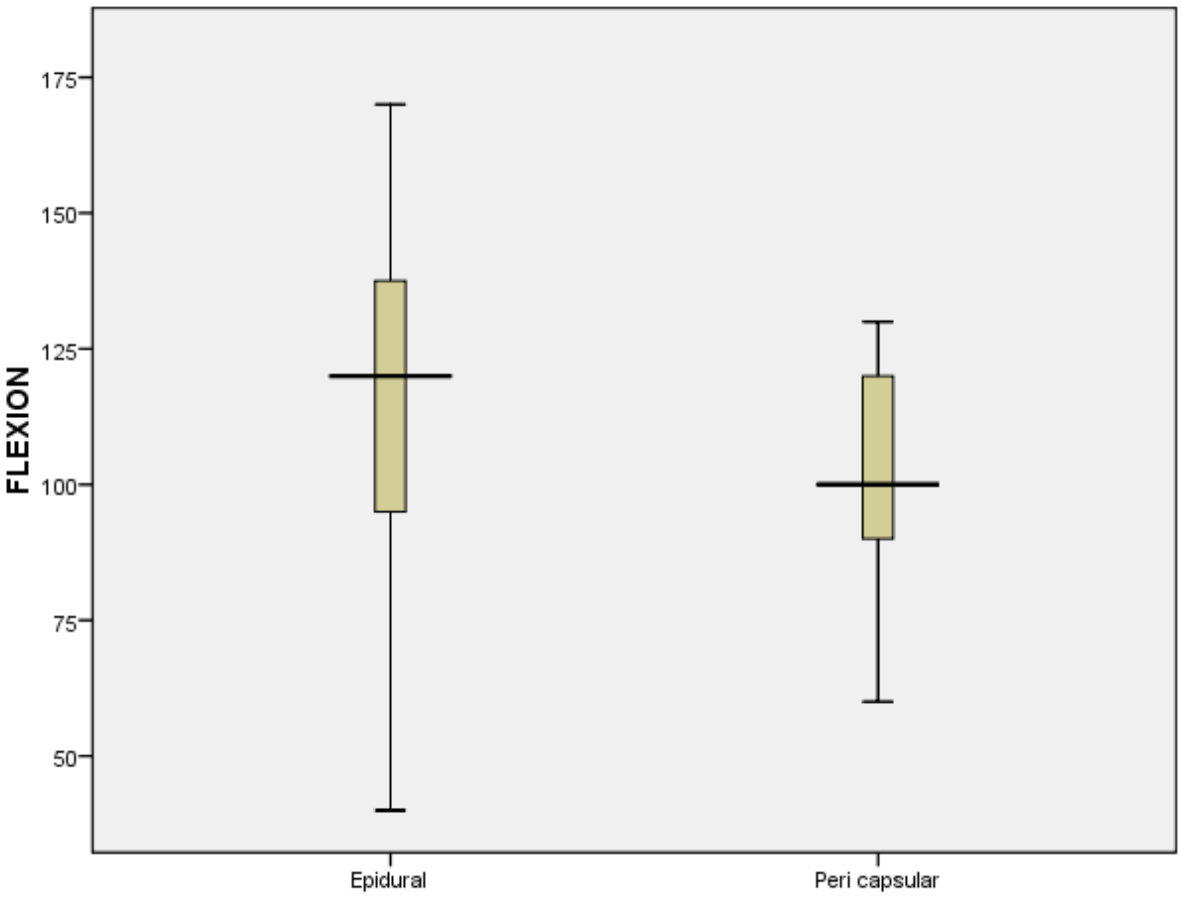
Pre operative assessment:

Pre operatively all the subjects were examined with special reference to range of movement and lag on straight leg raising in the sitting posture. In the group 1 (analgesic cocktail group) five and in the group 2 (epidural group) three had no fixed flexion deformity, the rest everyone had a deformity compromising extension. Fixed flexion deformity in the epidural group ranged from: 5-10 degrees three patients, 10-15 degrees three and three with 30 degrees. In the analgesic cocktail group this was 5-10

degrees three, 10-15 degrees four, and 20-30 degrees two. Range of movement: In the epidural group ten patients had 90 degrees and more flexion. One had less than 30 and one had a range 60 to 90 degrees movement. In the analgesic cocktail group it was 11 with the range 90 and more, two with less than 90 and one with a range 30-60 degrees (Figure 13). Range of movement was not severely affected as expected in the epidural group being associated with severe disease. In the epidural group three had full extension and in the analgesic cocktail group it was four. One of the patients in the analgesic cocktail had a hyper extension of 10 degrees. Pre operative range of movement was better in epidural but wasn't significant statistically (p value 0.315).

Variables	Epidural	Per capsular injection	P Value
Range of movement	115 ±34.99	102 ± 24.21	0.315

Table 8: Table showing range of movement statistical analysis



Graph 5: Graph showing range of flexion between the groups

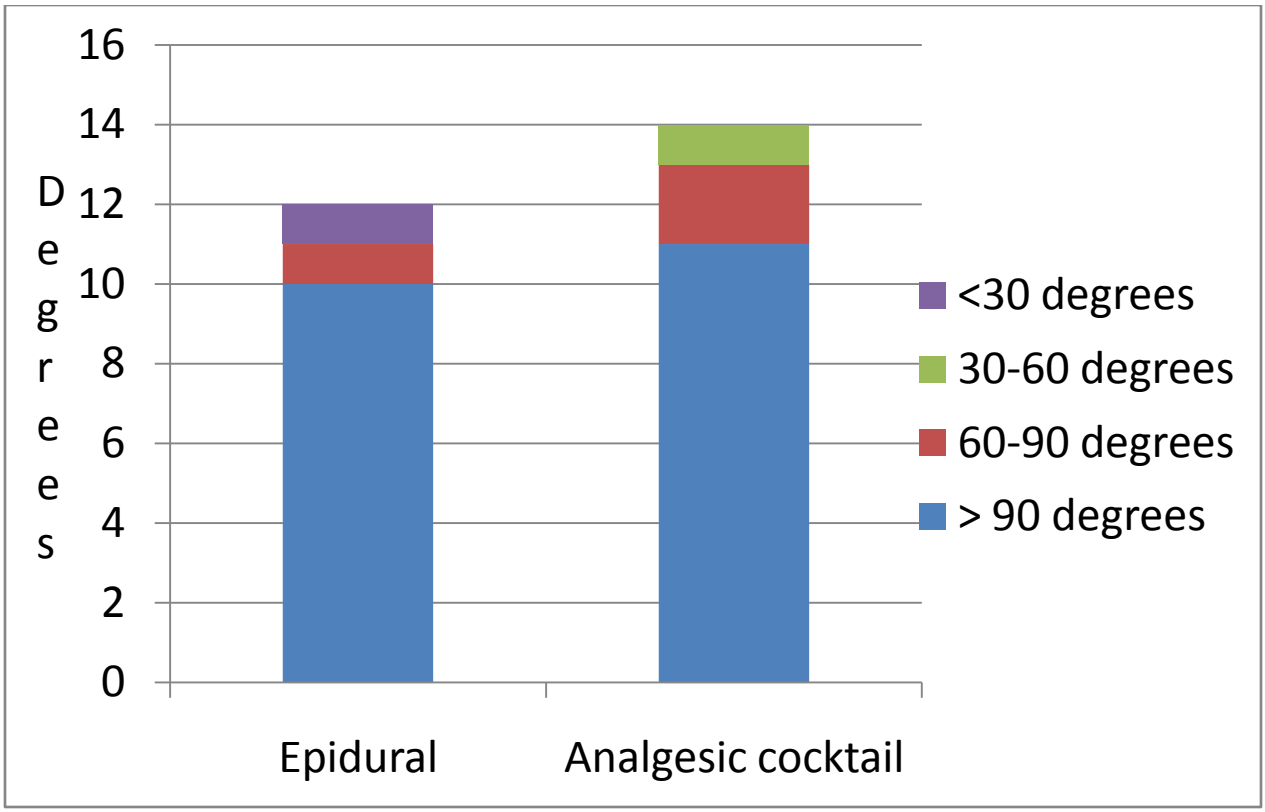


Figure 13: Bar diagram showing the pre operative range of movement and the analgesia given

Pre operative assessment of lag on extension of the knee in the sitting posture:

This was done in all subjects. In the epidural group only four had full extension with no lag when compared to seven in the analgesic cocktail group. Lag in the epidural group ranged from: Six had 5-10 degrees and two had more than 10 degrees. In the other group (Analgesic group) this was: Six with 5-10 degrees and one had more than ten degrees (Figure 14). Even though this was more in the analgesic cocktail group statistically this wasn't significant (p value 1.000).

Variables	Epidural	Per capsular injection	P Value
Lag on extension in sitting position	5.27 ±3.07	6.22 ± 5.24	1.000

Table 9: Tables showing statistical analysis

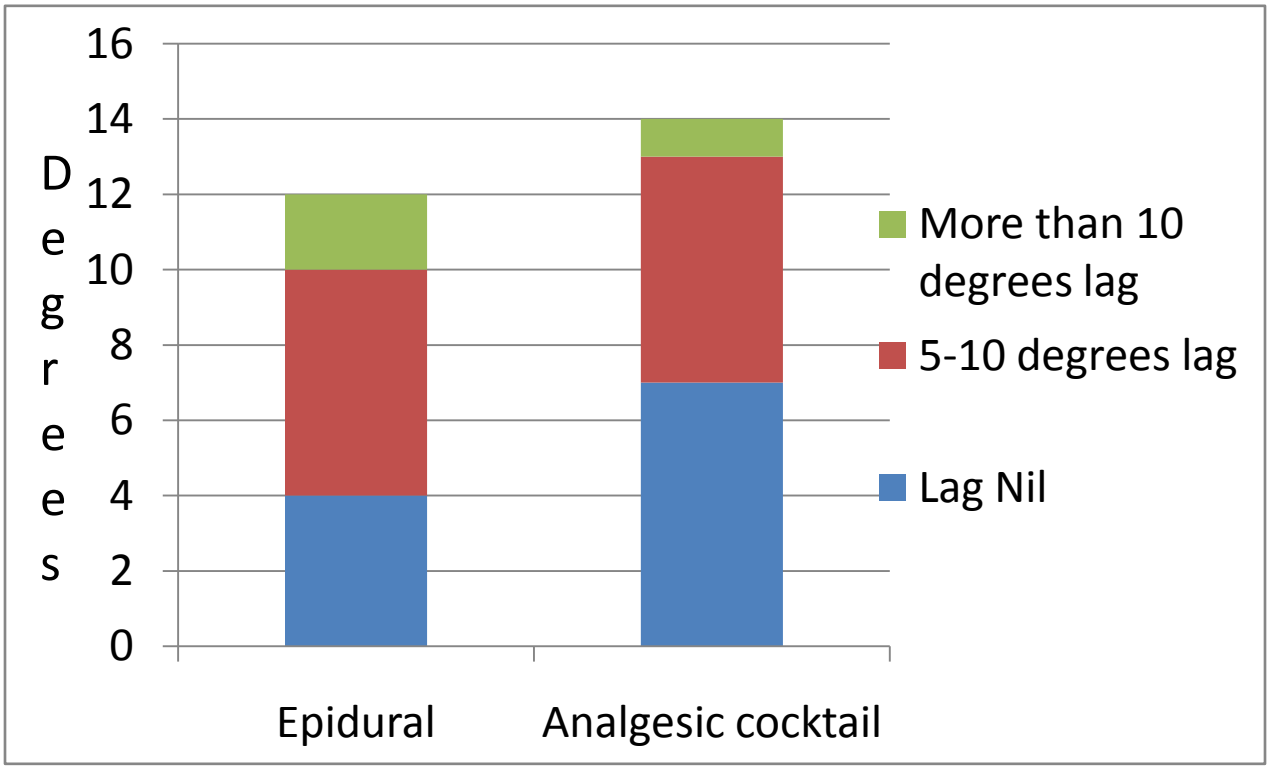


Figure 14: Bar diagram showing the pre operative lag in the sitting posture and the analgesia given

Anaesthesia used:

11 out of 12 in epidural and 13 out of 14 in the analgesic cocktail group was done under spinal anaesthesia. One of the patients in the epidural group was converted to general anaesthesia after a spinal and in the cocktail group one was done under general anaesthesia to start with.

Implants used:

The implant used included PS and CR knees, from 2 companies – Genesis II (Smith & Nephew, Memphis, TN, USA) and PFC Sigma CR fixed bearing (DePuy, Johnson & Johnson, Warsaw, IN, USA). The patella was replaced if a PS knee was used or if the patella was very badly eroded. In the epidural group eight had PFC and four had Genesis II while in the analgesic cocktail group eight had PFC and six Genesis II implants (Figure 15). Of this eight in the epidural and 12 in the analgesic cocktail had cruciate retaining and four in the epidural and two in the analgesic cocktail had posterior stabilized type of knees (Figure 16). Patellar replacement was done in six out of 12 in the epidural and five out of 14 in the analgesic cocktail group (Figure 17).

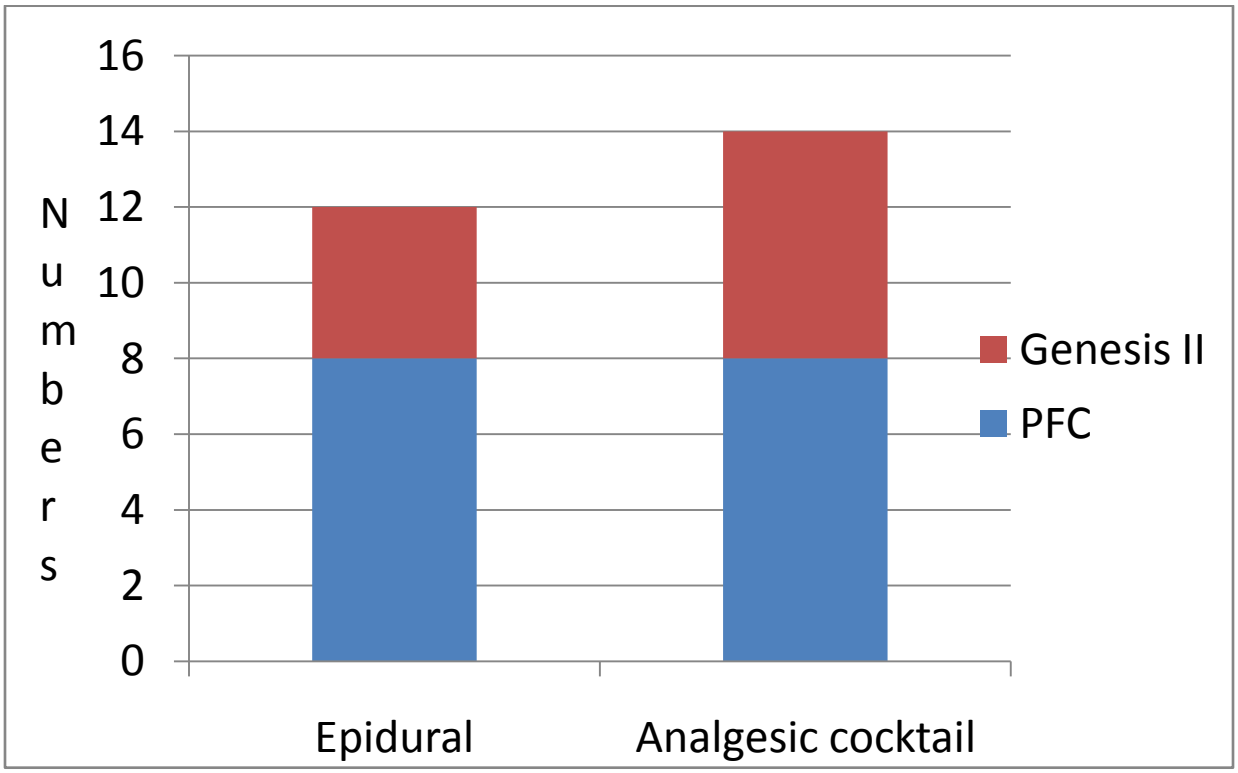


Figure 15: Bar diagram showing the different implants used and the analgesia given

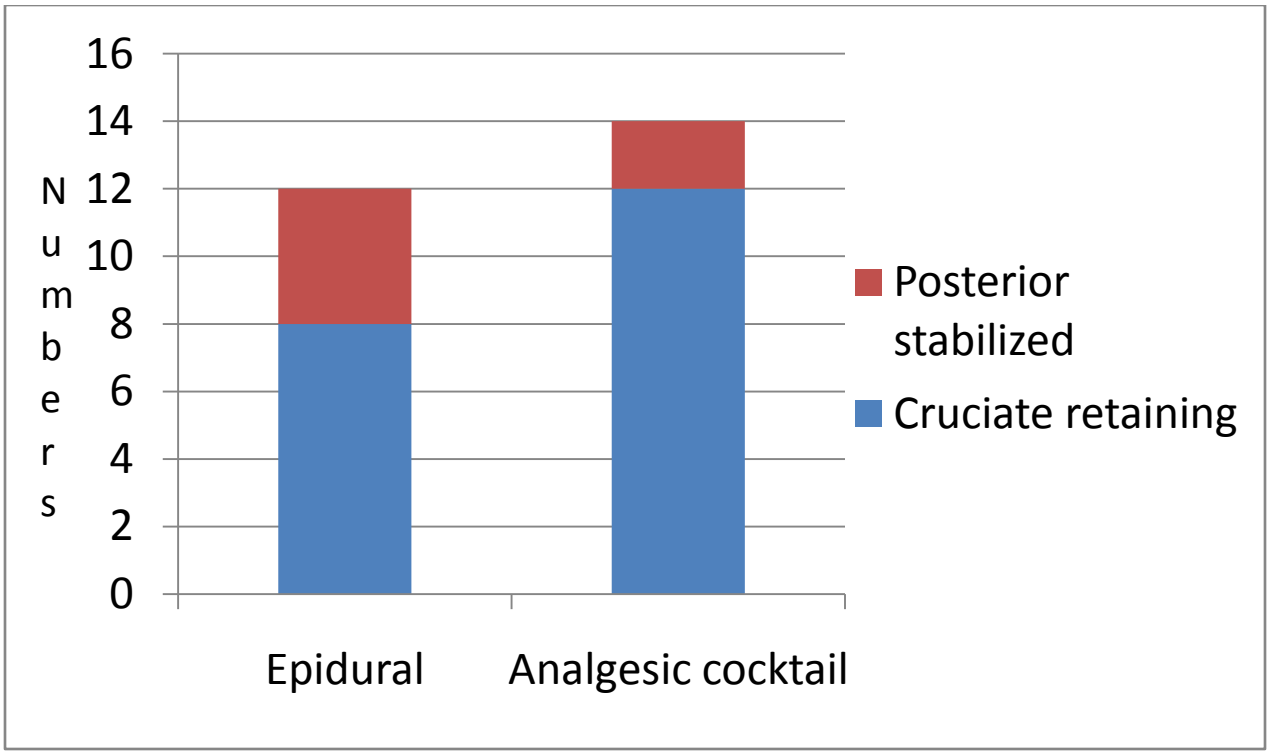


Figure 16: Bar diagram showing the different type of knees used and the analgesia given

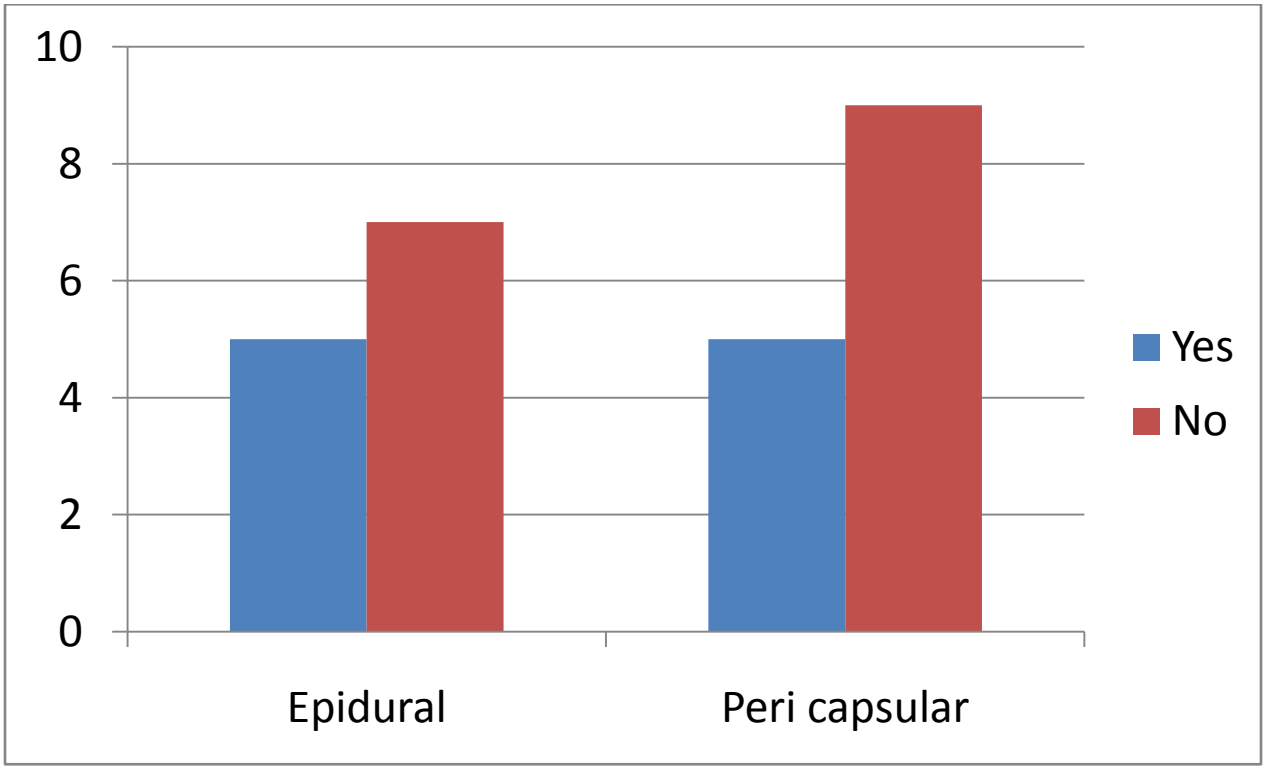


Figure 17: Bar diagram showing the number of patellar replacement among the analgesia groups

Variables	Epidural	Per capsular injection
Type of knee		
PFC	8 (67%)	8 (57%)
Genesis II	4 (33%)	6 (43%)
Type of knee		
CR	8 (67%)	12 (86%)
PS	4 (33%)	2 (14%)
Patella replacement		
Yes	5 (42%)	5 (36%)
No	7 (58%)	9 (64%)

Table 10: Table diagram showing the different implants and the different types of knees used and the analgesia given

Pain score:

Pain experienced by the patient using the NPS for pain was assessed postoperatively by the primary investigator on a daily basis. The average NPS score for the day was noted, as is also the maximum NPS score in the Q4H NPS score chart that is maintained by the pain nurses. Those patients on epidural, the pain score was documented by the pain clinic team of doctors too.

Pain score on a daily basis assessed by the principle investigator: The mean score on the first day in the epidural was seven and in the analgesic cocktail group it was 3.6. On the second day and third day it was 4.3 and 3.2 and 3.8 and 3 out of ten respectively. On the tenth day this almost became equal with the values being 2.4 and 2.7 respectively. The range in the epidural group on the first day was 1-10 with four out of 12 experiencing the maximum score of 10 while this was 0-9 in the analgesic cocktail and only one had the maximum pain score of nine. On the second and third days this was 2-9

and 0-6 and 2-8 and 0-6 respectively. On the day of discharge this was 1-4 and 0-6 out of ten in the numerical pain score (Figure 18). This points to the fact that in the initial days analgesic cocktail has a better pain control and as the days go by the pain equals in both the groups.

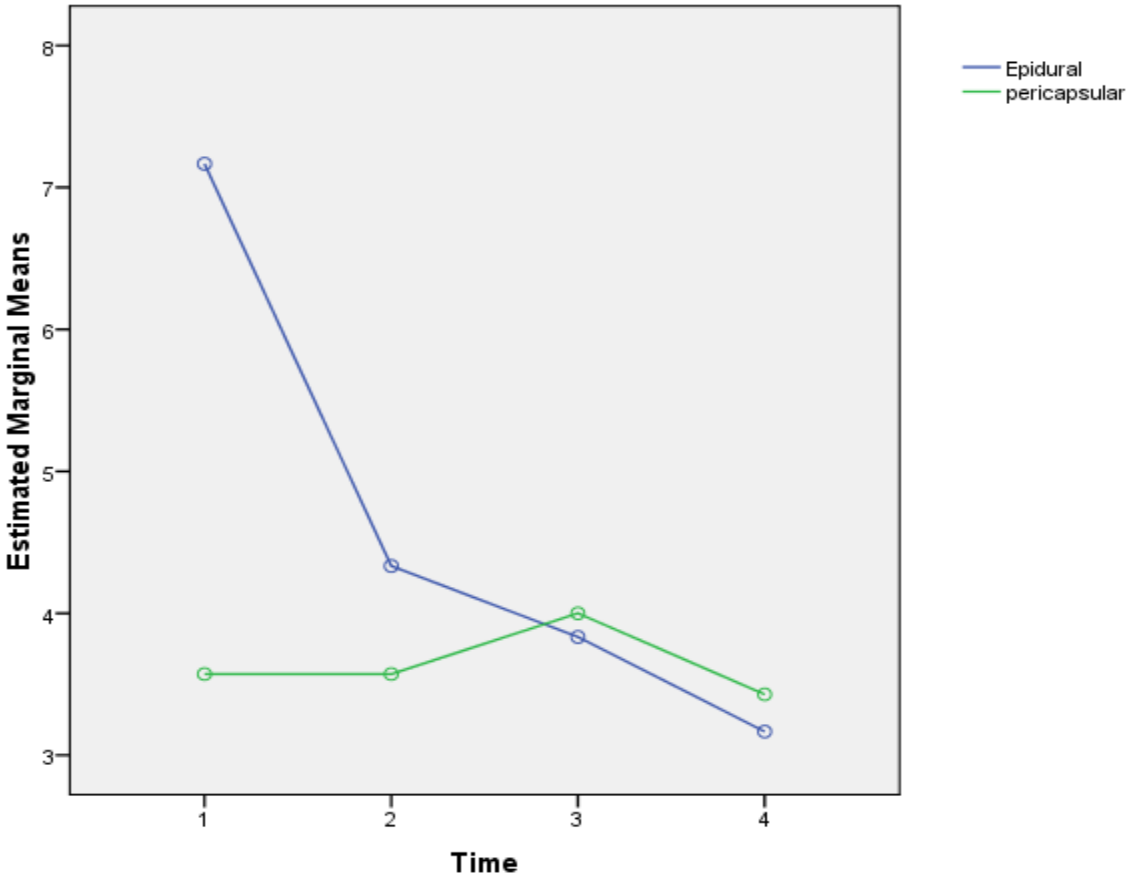
Nurse's chart: The mean pain score on the first day in the epidural group was 3.9 while this was 3.2 in the analgesic cocktail. The score in the following days were equal in both the groups. The range of pain varied from zero to 10 in the epidural compared to zero to eight in the analgesic cocktail group on the first day each having one patient recording maximum pain. In the following days the second day recorded 0-6 and 0-4, third and fourth days 0-4 and 0-3 respectively. This again proves the fact that in the initial day's analgesic cocktail has a better pain control than the epidural and as the days go by the pain equals in both the arms.

In the group receiving epidural first choice on having pain is increasing the dosage of epidural either giving as a bolus or the rate of infusion is increased. In the epidural group five patients received Inj.Morphine (Total of 25milli gram), eight had epidural top up (4-7ml/Hour) and four had epidural bolus (Total of 24milli gram). In two patients the epidural pump was not working and to these bolus, /top up and Inj Morphine were all used. One of the patients in this group, the epidural was continued for 36 hours due to severe pain. One of the patients had the epidural line coming out while turning on the second post operative day. In the cocktail group seven had received Inj Morphine (Total of 50mg).

Tests of within-Subjects Contrasts						
Source	Factor1	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Linear	50.481	1	50.481	6.231	.020
Time*Group	Linear	50.481	1	50.481	6.231	.020

Tests of between-Subjects Effects					
Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Intercept	1766.777	1	1766.777	191.774	.000
Epidural	24.931	1	24.931	2.706	.113
Error	221.107	24	9.213		

Table 11 & 12: Tables showing statistics.



Graph 6: Pain score plotted against the time period of both the groups

Pain score on the day of surgery

Variables	Epidural	Per capsular injection	P Value
Pain score on the day of surgery	7.17±2.79	3.57± 3.25	0.006

Table 13: Tables showing statistics and its analysis

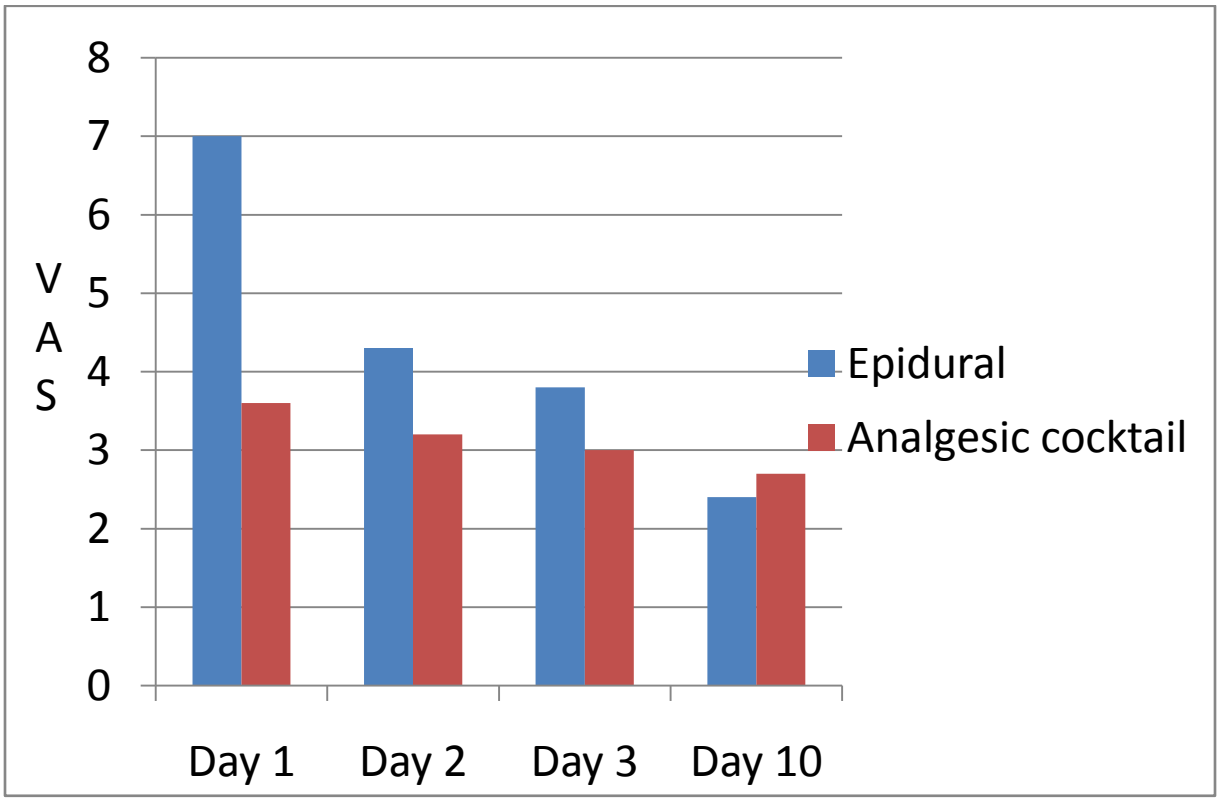


Figure 18: Bar diagram showing the Visual analog score during the first post operative days and the analgesia given

Morphine Injection and Epidural bolus combined:

Variables	Epidural	Per capsular injection	P Value
Analgesics supplemented	9 ± 3.74	7.14 ± 3.93	0.366

Table 14: Statistics and its analysis

Range of movement at time of discharge:

There was not any marked difference in the range of movement (ROM) at the time of discharge with the mean range of movement in the epidural group being 97 degrees when compared to 93 degrees in the analgesic cocktail group.

Tests of within-Subjects Contrasts						
Source	Factor1	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Linear	2038.507	1	2038.507	7.196	.013
Time*Epidural	Linear	430.815	1	430.815	1.521	.229
Epidural	Linear	1246.566	1	1246.566	2.15	.155

Table 15: Statistics and its analysis

Active straight leg raising with brace in the supine position:

33% in the epidural and 86% in the analgesic cocktail group was able to do active straight leg raise (SLR) with the help of a brace in the first post operative day itself (61 % of the study population). Another six patients in the epidural were able to do active

SLR in the second post operative day. Again one patient could do it on the third post op and another one could do it only on the day seven (Figure 19). In the analgesic cocktail group the rest two patients could do it on the second post operative day (Figure 20). One of the patients initially could do it but from the second post operative day onwards was not able and could do only after nine days, but on the day of discharge was able to do it actively. On statistical analysis, on the first day this was significant for the cocktail group, but as the days go by the significance became nil.

			95% Wald Confidence Interval		Hypothesis Test				95% Wald Confidence Interval for Exp(B)	
Parameter	B	Std. Error	Lower	Upper	Wald Chi-Square	df	Sig.	Exp(B)	Lower	Upper
(Intercept)	-2.486	1.2741	-4.983	.011	3.808	1	.051	.083	.007	1.011
Epidural	3.163	1.4706	.280	6.045	4.625	1	.032	23.635	1.324	422.050
Time	-.155	.5558	-1.245	.934	.078	1	.780	.856	.288	2.545
Epidural*Time	-.637	.6696	-1.949	.675	.906	1	.341	.529	.142	1.964

Table 16: Statistics and its analysis

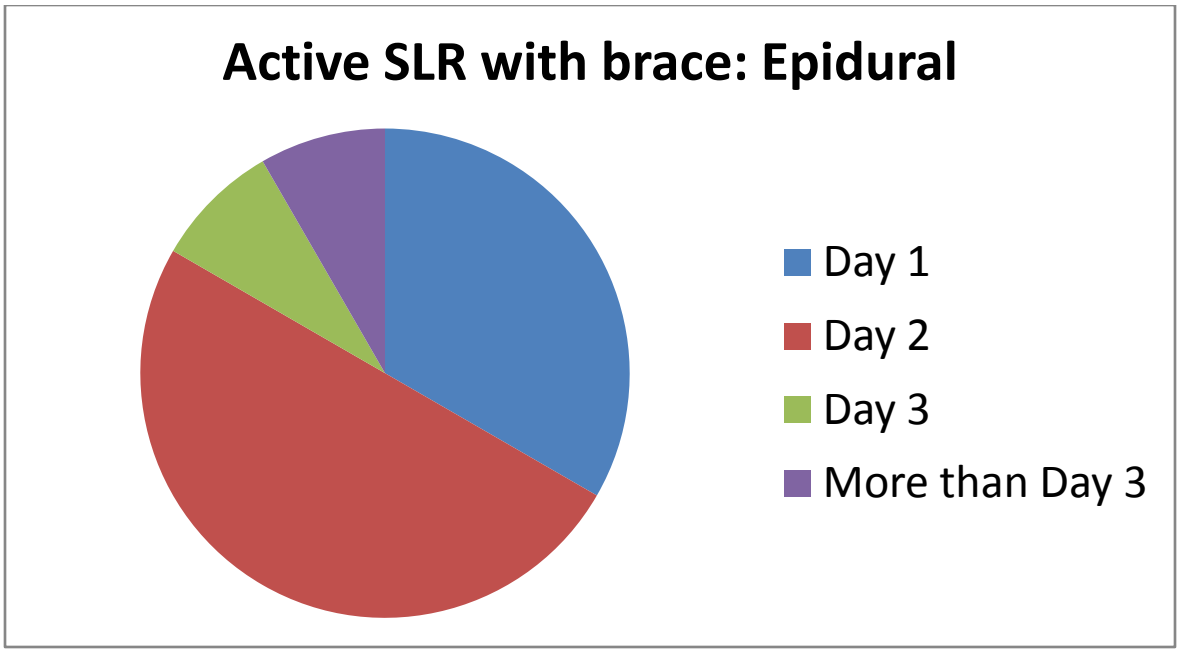


Figure 19: Pie diagram showing the time taken for patients to be able to do active straight leg raise by day1-4

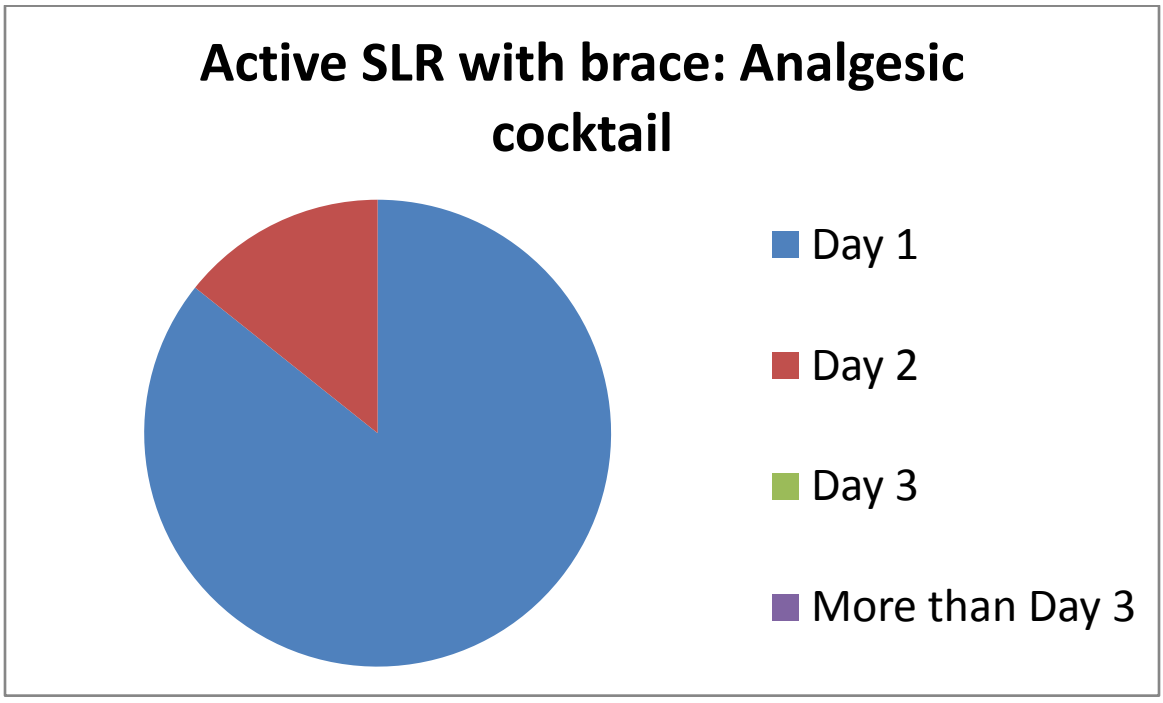


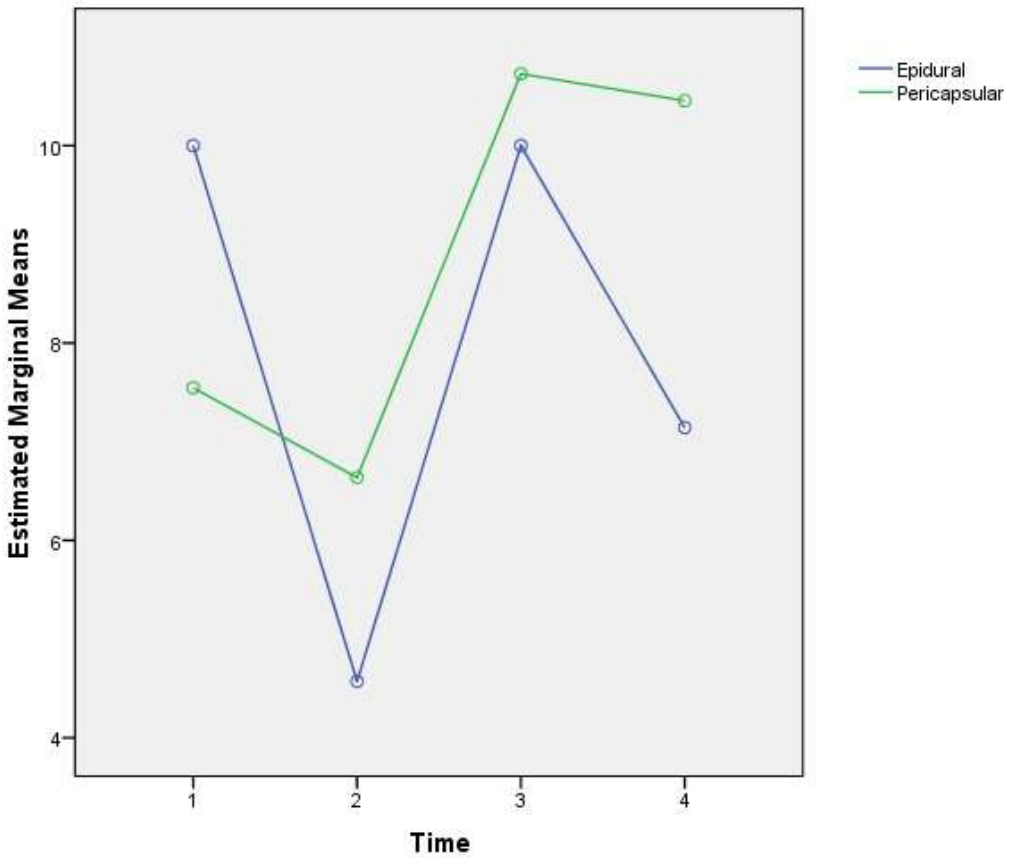
Figure 20: Pie diagram showing time taken for patients to be able to do active straight leg raise by day1-4

Lag on supine straight leg raising without the help of the brace:

33% in the epidural and 43% in the analgesic cocktail group were able to do straight leg raising without the help of the brace on the first post operative day. Another two in epidural and three in the analgesic cocktail were able to do it on the second day (Figure 21). The number of patients able to do it on third, fourth and fifth day in the analgesic cocktail group were two and one each while this in the epidural group was nil, one and two (Figure 22). 25 % of patients in the epidural were not able to do until seven days when compared to 7% in the analgesic cocktail.

Source	factor1	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Linear	20.023	1	20.023	.832	.375
Time* Epidural	Linear	54.489	1	54.489	2.265	.152
Epidural	Linear	14.243	1	14.243	0.70	.794

Table 17: Table showing statistical analysis



Graph 7: Lag on supine straight leg raising without the help of the brace plotted against the time period in days of both the groups

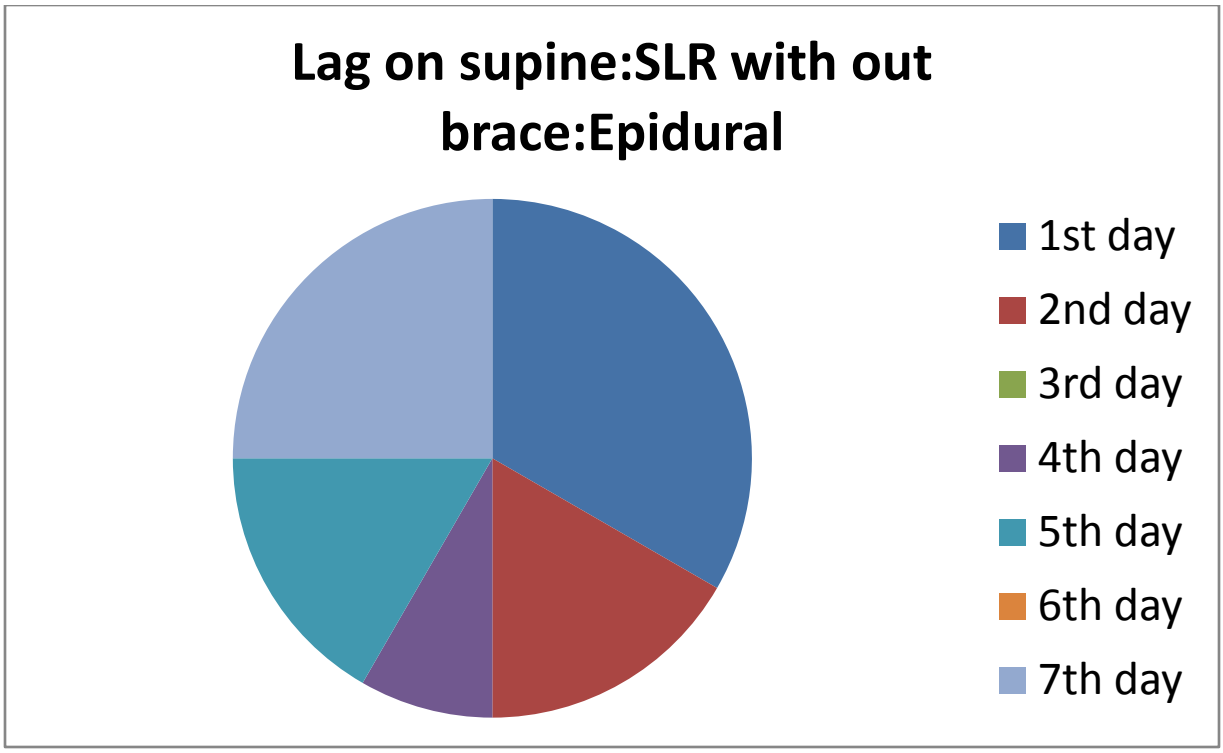


Figure 21: Pie diagram showing the number of days taken to do an active straight leg raising without a lag

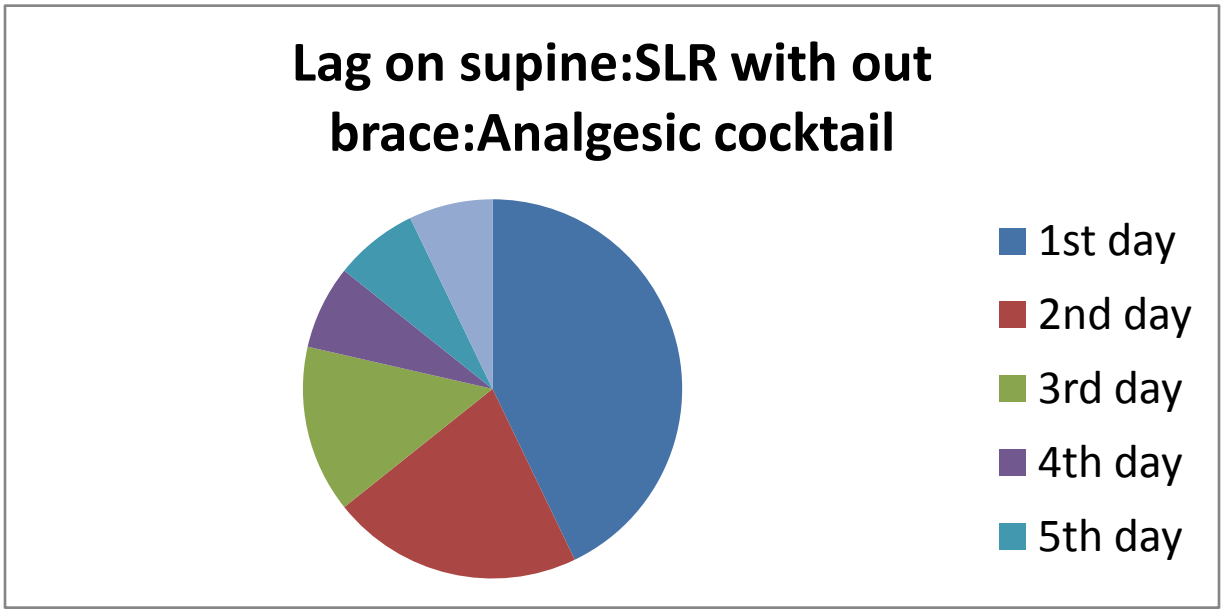


Figure 22: Pie diagram showing the number of days taken to do an active straight leg raising without a lag

Lag on extension in the sitting posture:

The mean lag in the epidural group was 8.3 and this in the analgesic cocktail group was five on the day of the discharge. 50% in the analgesic cocktail and 33% in the epidural attained a lag of less than five degrees by the time of the discharge. Lag was more in the epidural group but this was not statistically significant.

Source	Factor1	Type III Sum of Squares	Df	Mean Square	F	Sig.
Time	Linear	17.667	1	17.667	.091	.766
Time* Epidural	Linear	256.798	1	256.798	1.322	.263
Epidural	Linear	2691.943	1	2691.943	3.710	.068

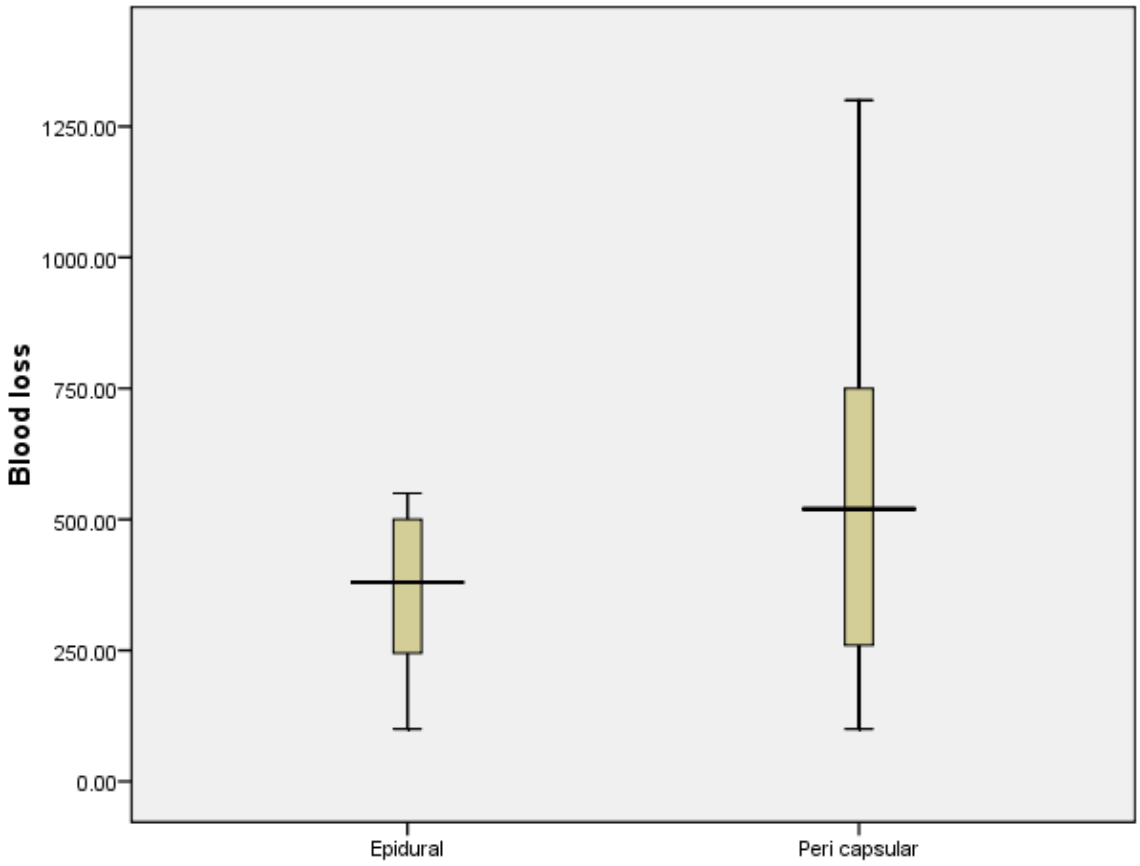
Table 18: Table showing statistical analysis

Blood loss:

The mean blood loss in the epidural group was 361 ml and in the analgesic cocktail it was 529 ml. This was in contrary to our thought as we were expecting less amount of blood loss in the analgesic cocktail. But this wasn't statistically significant (p value 0.167). The amount of blood or its products being transfused were equal in both the groups with a slight increased amount in the epidural group (Three out of 12 in the epidural compared to three out of 14 in the analgesic cocktail). Statistically this again was not significant (p value 0.167).

Variables	Epidural	Per capsular injection	P Value
Blood Loss	361 ± 161.58	529 ± 334.40	0.167

Table 19: Table showing statistics and analysis



Graph 8: Graph depicting amount of blood loss

Blood Transfusion:

Variables	Epidural	Per capsular injection	P Value
Blood transfusion Yes No	 3 (25%) 9 (75%)	 3 (21%) 11 (79%)	0.801

Table 20: Table showing statistics and analysis

Side effects:

Nausea and vomiting: Seven out of 12 (58 %) in the epidural had this complication while only five out of 14 (36 %) in the analgesic cocktail group. In the epidural 25 % had severe vomiting (Three out of 12) and this was only 14 % (Two out of 14) in the cocktail group. In both the groups there were almost equal numbers with moderate complication (Three out of 12 in the epidural and three out of 14 in pericapsular injection group) and one in the epidural had mild nausea.

Pruritis: This complication was almost equal in both the arms, three out of 12 in the epidural and three out of 14 in pericapsular injection group.

Urinary retention: Four in the epidural (33%) had mild discomfort, while this was 7% in the peri capsular group. One in the cocktail had moderate discomfort needing cold pack for voiding. Another patient in the cocktail group was catheterized while in the intensive care unit admission.

Respiratory depression: One in the analgesic cocktail (mild discomfort) and two in the epidural group (One mild and another moderate discomfort) had this complication.

One patient in the analgesic cocktail developed intra operative hypotension needing ICU admission for post operative monitoring and management.

One patient in the epidural group developed back pain needing close observation in the post operative period.

Side effects were higher in the epidural group but were not statistically significant.

Variables	Epidural	Per capsular injection	P Value
Nausea and Vomiting	7 (58%)	5 (36%)	0.448
Pruritis	3 (25%)	3 (21%)	1.000
Urinary retention	4 (33%)	2 (14%)	0.495
Respiratory depression	2 (17%)	1 (8%)	0.887
Cardio vascular	0	1 (8%)	-
Back ache	1 (8%)	0	-

Table 21: Table showing side effects

Other complications like infection, post operative bleeding or oozing, secondary surgery, meningitis, nerve palsy and death : Nil in both the arms.

Number of days taken to walk 50 meters without brace:

50 % of the epidural study group could walk 50 meters without the brace on the third day. Of the rest in the epidural: Two could do it on the fourth day, one each on the fifth and sixth day and the last two only after 8 days.57 % in the peri capsular group walked 50 meters on the third day, with fourth and fifth day having four and two. The time taken to walk 50 meters was less in the peri capsular group, though the difference was not statistically different (3.57 days Vs 4.17 days).

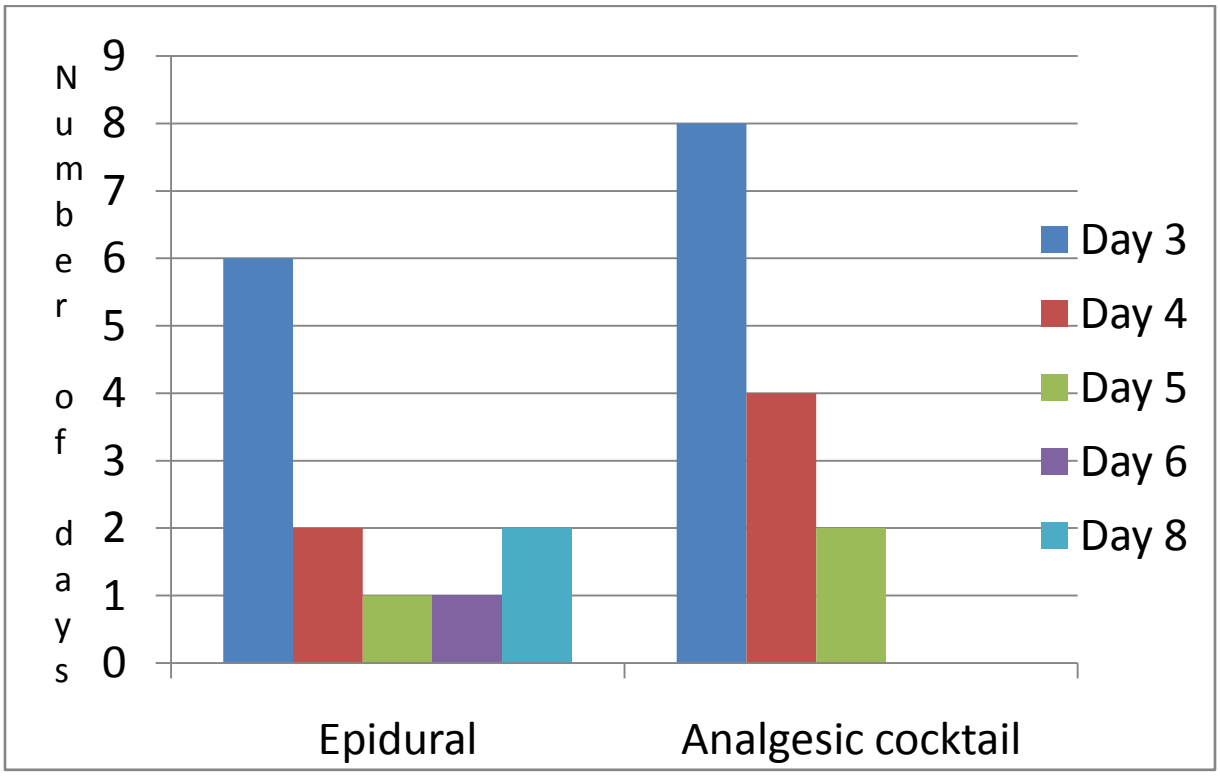


Figure 23: Bar diagram showing the time taken to walk 50 meters and the analgesia given

Number of days taken to climb a flight of 14 steps:

In the epidural group one could climb steps by fourth day. On the fifth day four patients and five on the sixth post operative day in the same group could climb. Two could do it only after 10 days. In comparison seven could do climbing only on the fifth post operative day in the peri capsular group. The rest could do it as four on sixth, two on seventh and one on the eighth day. The time taken to climb 14 steps was also less in the peri capsular group as compared to the epidural group but the difference was not statistically significant (5.79 days Vs 6.08 days).

Days taken to walk 50 m

Variables	Epidural	Per capsular injection	P Value
Days taken to walk 50 m	4.17 ± 1.69	3.57 ± 0.756	0.247

Days taken to climb 14 steps

Variables	Epidural	Per capsular injection	P Value
Days taken to climb 14 steps	6.08 ± 1.73	5.79 ± 0.975	0.587

Table 22 & 23: Table showing statistics and analysis

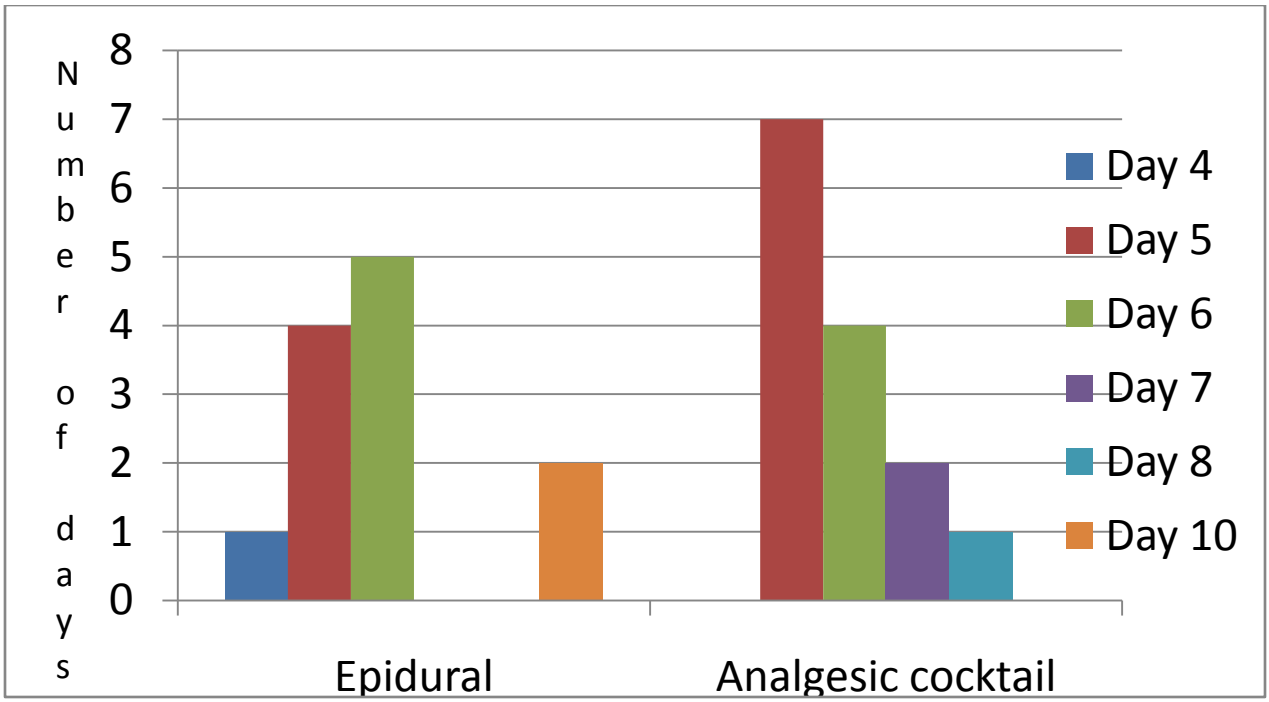


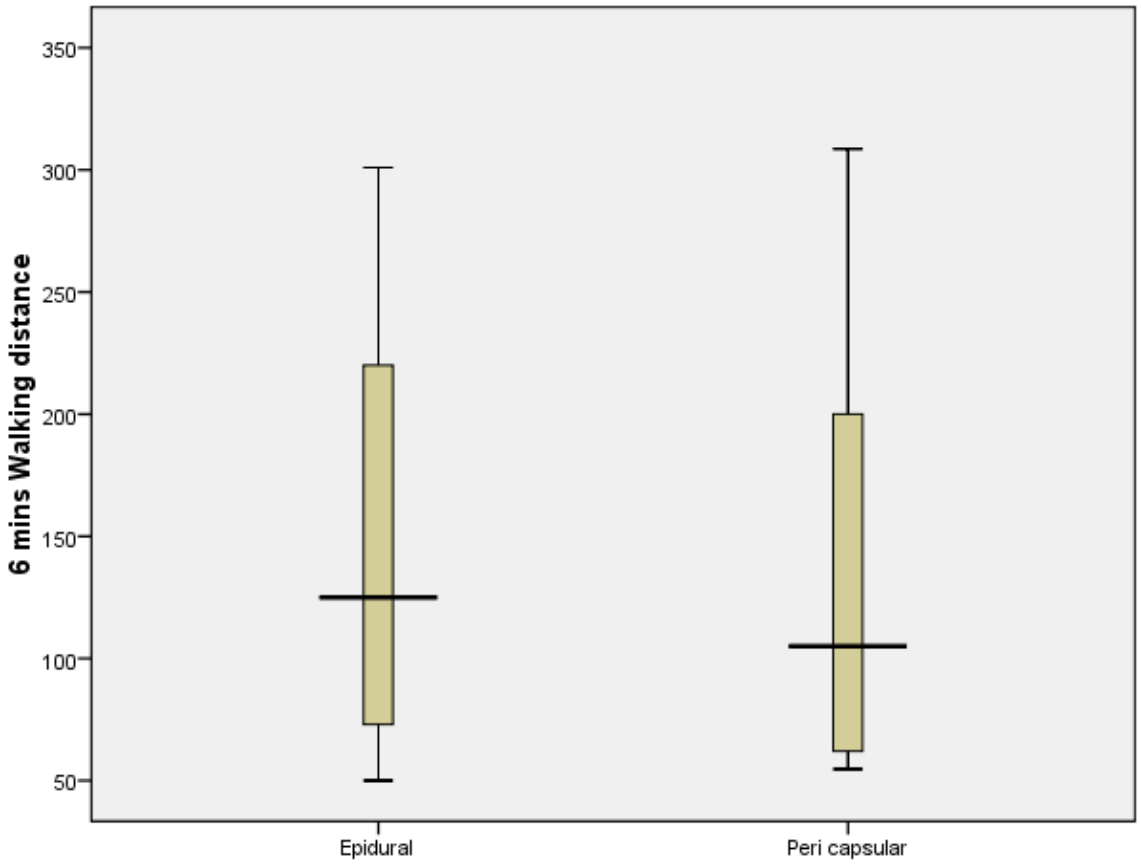
Figure 24: Bar diagram showing the time taken to climb 14 steps and the analgesia given

Distance walked in six minutes on Day 10:

The mean distance walked on the day of discharge (10 th post operative day) for the epidural group was 142.5 meters and for the analgesic cocktail it was 135 meters. This difference was not statistically significant (p value 0.796).

Variables	Epidural	Per capsular injection	P Value
Distance walked in six minutes on Day 10	142.56 ± 80.93	135.14 ± 80.18	0.796

Table 24: Table showing statistics and analysis



Graph 9: Graph depicting 6 minutes walking capacity

DISCUSSION

DISCUSSION

Total knee arthroplasty is one of the common arthroplasty surgeries done worldwide. Postoperative pain after total knee replacement (TKR) is a primary concern to patients and a focus of several recent research papers. Several techniques such as patient controlled analgesia, femoral nerve blocks, epidural analgesia and periarticular injection of medications have been reported.

Middle aged males who were manual labourers and those involved in heavy duty are thought to be more prone to degenerative arthritis. Our study was aimed at studying the efficacy of periarticular infiltration of a cocktail of drugs in controlling pain and enabling early functional recovery after total knee arthroplasty for those patients presenting to a tertiary hospital with degenerative arthritis during the period October 2013 to September 2014. We studied 26 cases of patients who had undergone total knee replacement surgery. The study shows that the periarticular infiltration is significantly better than the epidural injection in the first 24 hours after the surgery. Even after the first 24-48 hours, when we would expect the analgesic effect of the injection to wear out, the pain scores were consistently less in the peri articular injection group than in the epidural group. Functional ability in the first 24 hours was also significantly better in the peri articular injection group.

An additional advantage of the peri articular injection over the epidural anaesthesia is the reduced incidence of side effects like nausea, vomiting and pruritis. Additionally, mobilization is easier, as there are no catheters restricting the patient.

Arun Mullaji [7] in 2009 reviewed the effectiveness of a mixture of opioid, corticosteroid and a local anesthetic for periarticular injection in patients undergoing bilateral TKR. They injected one of the two knees with the drug cocktail. They reported significantly lower pain scores and better quadriceps recovery on the side that had periarticular injection of the anesthetic cocktail, as compared to the side that did not have the injection.

Thorsell et al [8] in his comparative study on total knee arthroplasty patients using local infiltration anaesthesia technique with Ropivacaine, Ketorolac and Adrenaline to epidural anaesthesia reported earlier mobilization in the group treated with local infiltration technique. They concluded that this technique also offered better patient satisfaction and hence was better for postoperative pain relief than epidural anaesthesia**.**

Nattapol Tammachote et al [13] compared the pain control effect of intrathecal morphine and multimodal drug injections in patients undergoing total knee arthroplasty. They found that though initially there was no difference between the two modalities, 12 – 16 hrs postoperatively, the intrathecal group consumed significantly more Ketorolac and that the side effects of nausea and vomiting was also more in this group compared to the group treated with multimodal drug injections.

Spreng et al [9] compared the efficacy of periarticular infiltration anaesthesia and epidural anaesthesia in total knee arthroplasty patients and reported that epidural anaesthesia provided better pain relief in the immediate postoperative period, where as local infiltration anaesthesia provided better pain relief after the initial 24 hours.

The above observations are contrary to what was found in our study, where we found better relief of pain, with periarticular injection in the first 24 hours. The level of analgesia was significantly better for the remaining hospital stay as well. Early functional recovery was possible with peri articular injection, though both groups were able to climb 14 steps by the 5th postoperative day. The reason for the prolonged beneficial effect of the peri articular injection has not been fully explained by other investigators. Several theories have been postulated. It is possible that due to the good reduction in pain in the immediate postoperative period, the neural sensitization is minimized. The steroid in the cocktail could also have a role in reducing the inflammatory pain postoperatively. In both groups, adequate control of pain provided the patient an opportunity to participate in the physiotherapy programme at an early stage and attain functional independence within 4- 5 days.

LIMITATIONS

LIMITATIONS

The selected samples in the cocktail group comprised of solely patients affected with osteoarthtritis whereas, in the epidural group there were samples representing rheumatoid and gouty arthritis. We are not sure whether this disparity in the sample would have influenced the results.

Further the preoperative morbidity of the subjects in the analgesic cocktail group was lesser compared to the subjects in the epidural group-through not significantly different. This again might have led to the slightly better outcome received with the analgesic cocktail treatment modality.

The pain threshold varies with subjects. Hence the pain perceived is not an objective measurement. A person with higher pain threshold might not report high scores in the pain scale. Objective measurement scales for pain being unavailable, we have tried to minimize the error by standardizing the pain recording procedure.

CONCLUSION

CONCLUSION

Primary Outcome:

1. The pain relief on the day of surgery (day 1) was significantly better in patients who received peri capsular injection as compared to those who used the epidural injection for postoperative pain relief.

2. The pain following knee replacement over the remaining days (days 2-10) was better in those who received peri capsular injection for pain control, but the difference was not statistically significant.

3. The ability to do a straight leg raise with a brace on day one of the surgery was significantly better in those who received peri capsular injection for pain relief, as compared to those on epidural infusion. This difference was not statistically significant from the second day onwards.

4. The time taken to walk 50 meters was less in the peri capsular group, though the difference was not statistically different (3.57 days Vs 4.17 days).The time taken to climb 14 steps was also less in the peri capsular group as compared to the epidural group but the difference was not statistically different (5.79 days Vs 6.08 days).

5. The post operative range of movement and the distance walked in 6 minutes on the day of discharge (Day 10) was marginally better in the epidural group - though the difference was not significant.

Secondary Outcomes:

1. Patients who received epidural infusion for postoperative pain control required more medications as supplements - as evidenced by higher incidence of bolus injections/increased infusion rates /morphine injections (The difference being not significant).

2. Side effects including nausea, vomiting, pruritis, urinary retention, and respiratory depression were significantly higher in the epidural group as compared to those who received the analgesic cocktail injection.

3. Blood loss collected in closed suction drainage: This was significantly higher in those who received peri capsular injections, but the numbers requiring blood or blood products for transfusion were equal among both groups.

BIBLIOGRAPHY

BIBLIOGRAPHY

1. Anne Weber MD,* Roxane Fournier MD,* Nicolas Riand MD, † Zdravko Gamulin MD*: Duration of analgesia is similar when 15, 20, 25and 30 mL of ropivacaine 0.5% are administered via a femoral catheter: CAN J ANESTH 2005 / 52: 4 / pp 390–396.

2. Parvizi J, Miller AG, Gandhi K.: Multimodal pain management after total joint Arthroplasty: J Bone Joint Surg Am.2011 Jun 1; 93(11):1075-84.

3. Singelyn FJ, Deyaert M, Joris D, Pendeville E, Gouverneur JM.:Effects of intravenous patient-controlled analgesia with morphine, continuous epidural analgesia, and continuousthree-in-one block on postoperative pain and knee rehabilitation after unilateral total knee arthr oplasty.: Anesth Analg 1998 Jul;87(1):88-92.

4. Chaumeron A, Audy D, Drolet P, Lavigne M, Vendittoli PA.: Periarticular injection in knee arthroplasty improves quadriceps function.: Clin Orthop Relat Res.2013 Jul;471(7):2284-95.

5. Kerr DR, Kohan L.: Local infiltration analgesia: a technique for the control of acute postoperative pain following knee and hip surgery: a case study of 325 Patients: Acta Orthop 2008 Apr; 79(2):174-83.

6. Aditya V. Maheshwari MD, Yossef C. Blum MD, Laghvendu Shekhar MD, Amar S. Ranawat MD, Chitranjan S. Ranawat MD : Multimodal Pain Management after Total Hip and Knee Clin Orthop Relat Res (2009) 467:1418–1423.

7. Mullaji A, Kanna R, Shetty GM, Chavda V, Singh DP.:Efficacy of periarticular injection of bupivacaine, fentanyl, and methylprednisolone in total knee arthroplasty:a prospective, randomized trial.: J Arthroplasty.2010 Sep;25(6):851-7.

8. Thorsell M, Holst P, Hyldahl HC, Weidenhielm L:
Pain control after total knee arthroplasty:
a prospective study comparing local infiltration anesthesia and epiduralanesthesia.Orth opedics.2010 Feb; 33(2):75-80.

9. Spreng UJ, Dahl V, Hjall A, Fagerland MW, Raeder J.: High volume local infiltration analgesia
combined with intravenous or local ketorolac+morphine compared withepidural analgesia after total knee arthroplasty: Br J Anaesth. 2010 Nov; 105(5):675-82.

10. Sean VW, Chin PL, Chia SL, Yang KY, Lo NN, Yeo SJ.:Single-dose periarticular steroid infiltration for pain management in total knee arthroplasty: a prospective, double-blind, randomized controlled trial.: Singapore Med J. 2011 Jan;52(1):19-23.

11. Scott CE, Streit J, Biant LC, Breusch SJ.: Periarticular infiltration in total hip replacement: effect on heterotopic ossification, analgesic requirements and Outcome:

Arch Orthop Trauma Surg 2012 May; 132(5):703-9. doi: 10.1007/s00402-011-1453-8. Epub 2012 Jan 6.

12. Yuenyongviwat V, Pornrattanamaneewong C, Chinachoti T, Chareancholvanich K.: Periarticular injection with bupivacaine for postoperative pain control in total knee replacement: a prospective randomized double-blind controlled trial.: Adv Orthop. 2012; 2012:107309. doi: 10.1155/2012/107309. Epub 2012 Oct 22.

13. Nattapol Tammachote MD, MSc, Supakit Kanitnate MD,Sudsayam Manuwong MD, Thanasak Yakumpor MD,Phonthakorn Panichkul MD: Is Pain After TKA Better with Periarticular Injection or Intrathecal Morphine?: Clin Orthop Relat Res (2013) 471:1992–1999.

14. Crowley C, Dowsey MM, Quinn C, Barrington M, Choong PF.: Impact of regional and local anaesthetics on length of stay in knee arthroplasty.: ANZ J Surg. 2012 Apr; 82(4):207-14. doi: 10.1111/j.1445-2197.2011.05991.x. Epub 2012 Feb 3.

15. Gibbs DM, Green TP, Esler CN.: The local infiltration of analgesia following total knee replacement: a review of current literature. J Bone Joint Surg Br. 2012 Sep; 94(9):1154-9. doi: 10.1302/0301-620X.94B9.28611.

16. Wylde V, Gooberman-Hill R, Horwood J, Beswick A, Noble S, Brookes S, Smith AJ, Pyke M, Dieppe P, Blom AW.: The effect of local anaesthetic infiltration on chronic

pain after lower limb replacement: a protocol for a double blind randomized controlled trial: BMC Musculoskelet Disord. 2011 Feb 26; 12:53.

17. Noble PC, Scuderi GR, Brekke AC, Sikorskii A, Benjamin JB, Lonner JH, Chadha P, Daylamani DA, Scott WN, Bourne RB. Development of a Knee Society Knee Scoring system. Clin Othop Relat Res. 2012; 470: 20-32.

APPENDIX

APPENDIX

1. Institutional review board (IRB) clearance form

2. Proforma

3. Anti coagulation protocol

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

Dr. George Thomas, D Ortho., Ph D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

February 1, 2014

Dr. Ajith. K
PG Registrar
Department of Orthopaedics Unit 2
Christian Medical College, Vellore 632 004

Sub: **Fluid Research grant project:**
Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine? - A Randomised Control Trial
Dr. Ajith. K, PG Registrar. Orthopaedics - II, Dr. Pradeep Poonnoose, Dr. Anil Thomas Oommen, Dr. Vignesh Prasad, Orthopaedics, Dr. Sajan Philip George, Anaesthesia.

Ref: IRB Min. No 8516 [INTERVEN] dated 30.10.2013

Dear Dr. Ajith. K,

I enclose the following documents:-

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Pradeep Poonnoose, Orthopaedics, CMC

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

Dr. George Thomas, D Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

February 1, 2014

Dr. Ajith. K
PG Registrar
Department of Orthopaedics
Christian Medical College
Vellore 632 004

Sub: **Fluid Research grant project:**
Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine? - A Randomised Control Trial
Dr. Ajith. K, PG Registrar. Orthopaedics - II, Dr. Pradeep Poonnoose, Orthopaedics, Dr. Sajan Philip George, Anaesthesia, Dr. Anil Thomas Oommen, Dr. Vignesh Prasad, Orthopaedics.

Ref: IRB Min. No 8516 [INTERVEN] dated 30.10.2013

Dear Dr. Ajith. K,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine?" on October 30th 2013.

The Committee reviewed the following documents:

1. IRB application format
2. Curriculum Vitae' Drs. Ajith. K, Pradeep Poonnoose, Sajan Philip George, Anil Thomas Oommen, Vignesh Prasad
3. Informed Consent form (English, Tamil & Hindi)
4. Consent form (English, Tamil & Hindi)
5. No of documents 1-4

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

The following Institutional Review Board (Research & Ethics Committee) members were present at the meeting held on October 30th, 2013 at 9.45 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Other Affiliations
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB.	External, Clinician
Dr. B. Poonkuzhali	M Sc, PhD	Professor, Haematology, CMCH.	Internal, Basic Medical Scientist
Dr. Asha Mary Abraham	MBBS, MD, PhD	Professor, Virology, CMCH.	Internal, Clinician
Dr. Molly Jacob	MBBS, MD, PhD	Professor, Biochemistry, CMCH.	Internal, Clinician
Dr. B.S. Ramakrishna	MBBS, MD, DM, PhD, FAMS, FA Sc, AGAF, FNA	Retired Professor, Vellore	External, Clinician
Dr. Anuradha Bose	MBBS, DCH, MD,MRCP, FRCPCH	Professor, Child Health, CMCH.	Internal, Clinician
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, CMCH.	Internal, Clinician
Dr. Vinod Joseph Abraham	MBBS, MD, MPH	Professor, Community Medicine, CMCH.	Internal, Clinician
Dr. Sukriya Nayak	MBBS, MS	Professor, General Surgery, CMCH	Internal, Clinician
Dr. Deepak Abraham	MBBS, MS	Professor, Endocrine Surgery, CMCH.	Internal, Clinician
Rev. Dr. T. Arul Dhas	M.Sc, BD, DPC, PhD (Edin)	Chaplaincy Department, CMCH.	Internal, Social Scientist

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Dr. George Thomas, D Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMCH.	Internal, Basic Medical Scientist
Dr. Binu Susan Mathew	MBBS, MD	Associate Professor, Clinical Pharmacology CMCH.	Internal, Pharmacologist
Mrs. Mary Johnson	M.Sc	Professor, Child Health Nursing	Internal, Nurse
Dr. B. Antonisamy	M.Sc, PhD, FSMS, FRSS	Professor, Biostatistics, CMCH, Member Secretary, Research Committee, IRB.	Internal, Statistician
Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay person
Mr. C. Sampath	B. Sc, BL	Legal Expert, Vellore	External, Legal Expert
Mrs. Selva Titus Chacko	M.Sc	Professor, Medical Surgical Nursing, CMCH.	Internal, Nurse
Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Scientist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMCH.	Internal, Legal Expert
Dr. Jayaprakash Muliyil	B. Sc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Dr. Nihal Thomas	MD MNAMS DNB(Endo) FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Secretary IRB (EC)& Dy. Chairperson (IRB), Prof. of Endocrinology & Addl. Vice Principal(Research), CMC.	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

The study will need to be submitted to a three monthly data-safety monitoring board (DSMB) review with duly filled in form found in the link
http://172.16.11.136/Research/IRB_Polices.html

In case of adverse event, it has to be reported to the IRB Compensation Committee with duly filled in SAE format addressed to Dr. Denise Fleming, Clinical Pharmacology, CMC as a hard copy. The soft copy addressed to saeclinpharm@gmail.com and copy to research@cmcvellore.ac.in.

The trial need to be registered with Clinical Trial Registry India (CTRI) http://ctri.nic.in before commencing.

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Fluid Grant Allocation:

A sum of 17,000 INR (Rupees Seventeen Thousand only) will be granted for 1 year.

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD, MNAMS, DNB(Endo), FRACP(Endo), FRCP(Edin), FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Pradeep Poonnoose, Orthopaedics, CMC
Dr. Binu Susan Mathew & Dr. Denise Fleming, Clinical Pharmacology, CMC

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

PROFORMA

Is early rehabilitation after total knee replacement better with Periarticular injection or Epidural Bupivacaine?

Name: Serial No:

Age: Sex: Hosp No:

Address:

Phone No:

Preoperative evaluation:

History of Diabetes Mellitus:

History of Rheumatoid arthritis:

- Walking distance: In meters
- Aid used: Yes/No
- Pain score pre-op:
- Analgesics used: Yes/No

Pre operative Knee society score:

Knee Score: Functional Score:

Pre operative:

- Lag on SLR: Sitting:
- Knee ROM: Passive:
    - Flexion:
    - Extension:

X-rays: Deformity:

Surgery Date:

Side operated : Right / Left knee :

- Anesthesia used: Spinal /GA:
- Components used: Type of knee used:

- Patella resurfacing done or not :+ / -
- Epidural injection: + / -
- Type and dosage:
- Local cocktail given or not : + / -

Post operative:

	DOS	1st POD	2nd POD	3rd POD		DOD	3 Months
Pain Score							
Pain Score: Nurses							
Pain Score: Anaesthesia							
Knee Flexion	NA	NA					
Active SLR with Brace (+/-):Supine							
Lag on supine: SLR without brace							
Lag on extension:While sitting	NA	NA					

Visual analog score:

1	2	3	4	5	6	7	8	9	10

Removed Epidural on:

How long the local act:

Injection Morphine used or not:

Dosage and time:

Epidural bolus given or not:

Dosage and time:

Blood loss:

Drainage tube:

1st Day:

2nd Day:

Blood and its products:

Peri-operative complications (+/-):

- Nausea:
- Vomiting:
- Pruritus:
- Urinary retention:
- Respiratory depression:
- Others:

Number of days taken to walk 50 m without brace:

Number of days taken to climb a flight of 14 steps:

Distance walked in 6 minutes:

Comments:

Knee Society Score

Pain:

- None:
- Mild/Occassional:
- Mild (Stairs only):
- Mild (Walking & Stairs):
- Moderate/Occassional:
- Moderate/Continual:
- Severe:

Flexion contracture in degrees:

5-10 / 10-15 / 15-20 / >20.

Extension Lag:

<10 / 10-20 / >20.

Total range of flexion:

Alignment:

Varus/Valgus:

In degrees:

Stability:

Antero-Posterior: <5 / 5-10 / 10+.

Medio-Lateral: <5 / 6-9 / 10-14 / 15+.

SCORE:

Functional:

Walking:

Un Limited:

>10 Blocks:

5-10:

<5:

House bound:

Unable:

Stairs:

Normal Up and Down:

Normal Up, Down with Rail:

Up and Down with Rail:

Up with Rail, Down Unable:

Unable:

Walking Aids Used:

None Used:

Use of Cane/Walking stick deducts:

Two Canes/Sticks:

Crutches/Frame:

SCORE:

Dept of Orthopaedics Unit II

Anticoagulation Protocol for THR/TKR/Pelvic fracture surgery

Preoperative Risk Assessment for Pulmonary Embolism:

1. Previous documented history of PE	
2. Previous documented history of thromboembolic events	
3. Maintenance treatment with anticoagulation	
4. Known hypercoagulable states – ➢ Malignancy	
➢ Estrogen use	
➢ Others- Polycythemia, Protein C , Protein S deficiency, antiphopholipid antibodies (h/o abortions), antithrombin deficiency, factor V Leiden, acquired/congenital thrombophilias, prothrombin mutation 20210A	
5. Documented family history of PE	
6. Limitations to mobility that would impair early adequate mobilisation post-surgery including nerve injuries/spinal injuries/cases requiring post op bed rest	
7. Marked obesity – BMI > 35	
8. Smoking	
9. Venous stasis	
10.IDDM (type I DM)	
11.Hormone replacement therapy/ OCP use (excluding low dose Progesterone only)	

Risk for pulmonary embolism	**Standard / High**

Preoperative Risk Assessment for Major Bleeding:

1. **Preoperative conditions**

a. Known bleeding disorder	
b. Anticoagulation therapy/high dose Aspirin/anti platelet agents	
c. History of bleeding on chemoprophylactic agents	
d. History of major GI bleed	
e. History of haemorrhagic shock	
f. History of other major bleeding event/menorrhagia	

2. **Perioperative events**

a. Revision THR/TKR	
b. Major surgical bleeding	
c. Other major bleeding episode	

Risk for Major Bleeding	**Standard / High**

<u>Final Categorization for chemoprophylaxis</u> (*Tick appropriate)*

- ☐ Aspirin alone for 6 weeks
- ☐ Clexane followed by aspirin after 10 days for 6 weeks
- ☐ None
- ☐ Other -

Assessed by -

Anticoagulation Chemoprophylaxis Protocol

[To be used ***ALWAYS*** in concurrence with Mechanical Prophylaxis]

I. Patients at ***standard risk of both PE and major bleeding:***

1. Aspirin, 150 mg (reduce to 75 mg if gastrointestinal symptoms develop), starting the evening of surgery, for 6 weeks.
2. Mechanical prophylaxis

II. Patients at ***elevated (above standard) risk of PE and at standard risk of major bleeding:***

1. Clexane , starting 12 to 24 hours postoperatively (or after an indwelling epidural catheter has been removed), for 10 days [20-40mg once daily sub cutaneous]
2. Aspirin, 150 mg (reduce to 75 mg if gastrointestinal symptoms develop), starting on day 10, for 6 weeks.
3. Mechanical prophylaxis

III. Patients at ***standard risk of PE and at elevated (above standard) risk of major bleeding:***

1. Mechanical prophylaxis *ONLY*
2. No chemoprophylaxis
3. If patient was pre-operatively on Aspirin , restart same dose after drain removal
4. If patient was pre-operatively on anticoagulation, restart same after drain removal

IV. Patients at ***elevated (above standard) risk of both PE and major bleeding:***

1. Discuss individual case with Dept of Haematology
2. Mechanical prophylaxis

Dept of Orthopaedics Unit II

Ward Protocol for post op mechanical DVT prophylaxis

- Active dorsiflexion and plantar flexion of ankle and toes and should be performed in sets of 10 to 20 every half hour
- Passive ankle dorsiflexion and plantar flexion with calf massage should be performed in sets of 10 to 20 every half hour
- Patient to be sat up and out of bed 4-5 times a day

DAY 1

Time	Calf pump	Active dorsiflexion & plantar flexion of ankle	Passive ankle mobilisation & calf massage	Signature	Time	Calf pump	Active dorsiflexion & plantar flexion of ankle	Passive ankle mobilisation & calf massage	Signature
7.00 am					7.00 am				
7.30 am					7.30 am				
8.00 am					8.00 am				
8.30 am					8.30 am				
9.00 am					9.00 am				
9.30 am					9.30 am				
10.00 am					10.00 am				
10.30 am					10.30 am				
11.00 am					11.00 am				
11.30 am					11.30 am				
12.00 pm					12.00 pm				
12.30pm					12.30pm				
01.00 pm					01.00 pm				
01.30 pm					01.30 pm				
02.00 pm					02.00 pm				
02.30 pm					02.30 pm				
03.00 pm					03.00 pm				
03.30 pm					03.30 pm				
04.00 pm					04.00 pm				
04.30 pm					04.30 pm				
05.00 pm					05.00 pm				
05.30 pm					05.30 pm				
06.00 pm					06.00 pm				
06.30 pm					06.30 pm				
07.00 pm					07.00 pm				
07.30 pm					07.30 pm				
08.00 pm					08.00 pm				
08.30 pm					08.30 pm				

DAY 2

Time	Calf pump	Active dorsiflexion & plantar flexion of ankle	Passive ankle mobilisation & calf massage	Signature	Time	Calf pump	Active dorsiflexion & plantar flexion of ankle	Passive ankle mobilisation & calf massage	Signature
7.00 am					7.00 am				
7.30 am					7.30 am				
8.00 am					8.00 am				
8.30 am					8.30 am				
9.00 am					9.00 am				
9.30 am					9.30 am				
10.00 am					10.00 am				
10.30 am					10.30 am				
11.00 am					11.00 am				
11.30 am					11.30 am				
12.00 pm					12.00 pm				
12.30pm					12.30pm				
01.00 pm					01.00 pm				
01.30 pm					01.30 pm				
02.00 pm					02.00 pm				
02.30 pm					02.30 pm				
03.00 pm					03.00 pm				
03.30 pm					03.30 pm				
04.00 pm					04.00 pm				
04.30 pm					04.30 pm				
05.00 pm					05.00 pm				
05.30 pm					05.30 pm				
06.00 pm					06.00 pm				
06.30 pm					06.30 pm				
07.00 pm					07.00 pm				
07.30 pm					07.30 pm				
08.00 pm					08.00 pm				
08.30 pm					08.30 pm				

DAY 3

Time	Calf pump	Active dorsiflexion & plantar flexion of ankle	Passive ankle mobilisation & calf massage	Signature	Time	Calf pump	Active dorsiflexion & plantar flexion of ankle	Passive ankle mobilisation & calf massage	Signature
7.00 am					7.00 am				
7.30 am					7.30 am				
8.00 am					8.00 am				
8.30 am					8.30 am				
9.00 am					9.00 am				
9.30 am					9.30 am				
10.00 am					10.00 am				
10.30 am					10.30 am				
11.00 am					11.00 am				
11.30 am					11.30 am				
12.00 pm					12.00 pm				
12.30pm					12.30pm				
01.00 pm					01.00 pm				
01.30 pm					01.30 pm				
02.00 pm					02.00 pm				
02.30 pm					02.30 pm				
03.00 pm					03.00 pm				
03.30 pm					03.30 pm				
04.00 pm					04.00 pm				
04.30 pm					04.30 pm				
05.00 pm					05.00 pm				
05.30 pm					05.30 pm				
06.00 pm					06.00 pm				
06.30 pm					06.30 pm				
07.00 pm					07.00 pm				
07.30 pm					07.30 pm				
08.00 pm					08.00 pm				
08.30 pm					08.30 pm				

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine?

Study Number:

Participant's name:

Date of Birth / Age (in years):

I (name) _____

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or legal rights [ ]

I understand that I will receive free treatment for any study related injury or adverse events but I will not receive any other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name: Left Thumb Impression

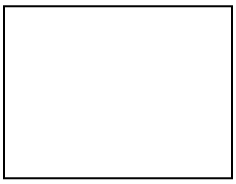
Signature:

Date:

Name of witness:

Relation to participant:

Date:



Christian Medical College, Vellore

Department of Orthopaedics

Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine?

Information sheet

You are being requested to participate in this study to assess the effectiveness of peri articular injection of a mixture of analgesic drugs (analgesic cocktail), in the management of pain after undergoing Total Knee replacement.

Currently, for immediate postoperative pain following a total knee replacement, we give a continuous injection of an analgesic medicine through a small tube inserted near your spinal cord. This is referred to as the "epidural infusion'. This is normally used for 48 hrs postoperatively. The new method of pain relief that we are trialing involves the injection of a mixture of drugs into the tissues around the joint (periarticular injection) at the time of surgery. It has been shown in studies that this is very effective in reducing the pain post operatively. We want to assess the efficacy of the new method of analgesia in our subset of patients undergoing total knee replacement. Hence we would like to compare the efficacy of this method with the current existing method of epidural infusion.

The surgical procedure is exactly the same. Instead of using epidural anaesthesia for pain relief we will be using an analgesic cocktail. We anticipate that this will give good pain relief, and thus a faster return to normal activities of daily living and a faster and more effective functional recovery is expected. We also anticipate fewer side effects like nausea, vomiting, itching etc, that are sometimes associated with epidural anaesthesia. No additional risk or discomfort is anticipated.

What does the cocktail consist of?

The Peri-capsular Cocktail of anaesthetic drugs used for pain control include

- 50ml 0.2% Ropivacaine
- 10 ml Saline
- 0.3 ml Noradrenaline (0.6mg)
- 40mg Depomedrol Acetate

- 10mg Morphine
- 30 mg Ketorelac
- 1 gm Cefazolin

Does this cocktail have any side effects?

No. They do not have any known side effects and has been in use for some time and results of the procedure have been published in other literature.

Can you choose which type of postoperative anaesthesia is going to be used for your surgery?

If you agree to participate in the study, you will be randomized by the investigator – and then you will receive either the epidural infusion or the pericapsular injection for pain relief. If you require any additional pain relief, this will be provided.

How long will the pain relief provided by the periarticular injection work for?

The periarticular injection should definitely provide you good pain relief for the first post operative day, and you will be encouraged to walk as soon as possible. Studies have shown that the pain relief on the subsequent days too been well.

What will happen of you have pain in spite of these methods?

The primary objective of postoperative analgesia is 'adequate pain relief'. If you are having "breakthrough pain" in spite of the epidural anaesthesia or the pericapsular injection, we will give additional injections which will help reduce pain. We will also put you on nonsteroidal anti-inflammatory agents like T. Aceclofenac which will also help in reduction of the pain.

If you take part what will you have to do?

You will be randomized into receiving either epidural infusion or the analgesic cocktail for post operative pain control. All other treatments that you were already on will be continued.

A doctor will monitor your pain and function periodically after the surgery. If you have any pain or any problems after the surgery, he will help you with your problem. The physiotherapist will help you walk post operatively, and we will monitor how soon you are able

to walk a distance of 50m, as well as climb a flight of 10 steps. After discharge, you will be expected to come for a review to the hospital three months after surgery, and thereafter as required by the surgeon.

If at any time experience any problem, you are expected to report this to the doctor, whose details are listed below.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are free to decide to withdraw from this study at any time prior to the surgery. If you do so, this will not affect your usual treatment at this hospital in any way. You will receive the current method of epidural anaesthesia for pain relief.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects such as allergic reaction or another unforeseen complication due to the study, these will be treated appropriately.

What happens after the study is over?

If the results of the study indicate that periarticular injection of the analgesic cocktail is as effective as the epidural injection, we would use this method as the preferred method for post operative pain relief in patients undergoing unilateral knee replacement. The results of the study will also be published in a peer reviewed journal.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal and you will not be identified in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please contact

Dr.Ajith.K,
Department of orthopaedics Unit 2,

Christian Medical College,
Vellore.
Phone no.08489646987
E-mail:ajith_ortho@yahoo.co.in

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine?

Study Number:

Participant's name:

Date of Birth / Age (in years):

शोधकार्य संबंधी अनुसंधान का अनुमति पत्र

मैं ..... (नाम) इस अनुसंधान के बारे में दिया गया पत्र पढ़ा है मेरा हर संदेह दूर किया है।
मैं यह जानता हूँ कि यह अनुसंधान में भाग लेना स्वैच्छिक है और बिना मेरे इलाज में कोई रुकावट के, मैं जब चाहूँ तो मैंने फैसला बदल सकता हूँ और इससे निकल सकता हूँ।
इस में भाग लेने के दौरान अगर कोई दुष्प्रभाव पड़े या कोई नयी होनी प्रकट हुई तो मुझे इसका मुफ्त इलाज मिलेगा। मैं यह जानता हूँ कि मुझे ऐसी अवस्था में कोई आर्थिक मुआवजा नहीं मिलेगा।
मुझे यह भी पता है कि अगर मैं इस में भाग नहीं लेता तो भी अनुसंधान से जुड़े लोग मेरे मेडिकल रेकार्ड देख सकते हैं।
मैं यह भी जानता हूँ कि मेरे निजी सूचनाओं को गोपनीय रखा जाएगा और प्रकाशित नहीं करेंगे।
मैं स्वेच्छया इस अनुसंधान में भाग लेने का निर्णय लेता हूँ।

नाम :
हस्ताक्षर :

साक्षी :
हिस्सेदार से संबन्ध :

Christian Medical College, Vellore
Department of Orthopedics

Is early rehabilitation after Total Knee replacement (TKR) better with Periarticular injection or Epidural Bupivacaine?

Information sheet

हम घुटनों के ऑपरेशन से दर्द कम करने के लिए कई दवाइयों के एक मिश्रण की प्रभाव का जाँच कर रहे हैं। आप को इस अनुसंधान में भाग लेने का निमंत्रण देना है और आप से बिनती है कि आप इस में भाग लें।

अब इस ऑपरेशन के बाद दर्द कम करने के लिए दर्द निवारक दवाई आपको मेरुदण्ड के पास एक ट्यूब से करीब अठतालिस घण्टों को अविच्छिन देना है। यह जो नया तरीका है इस में दवाइयों के मिश्रण आपको ऑपरेशन के बिल्कुल ही आपके घुटनों के आसपास इन्जेक्शन के रूप में दिया जाएगा। कई अनुसंधानों में यह एक बेहतर तरीका माना गया है। इसलिए हम यह तरीका अपनाकर पुराने तरीके की तुलना करना चाहते हैं। ऑपरेशन में कोई फर्क नहीं होगी और हमारा मानना यह है कि दर्द कम होने के साथ ही यह तरीका आपको जल्दी क्रियात्मक बना सकते है। इसके अलावा इससे आपको उल्टी खुचली आदी दुष्प्रभाव होने की संभावना भी बहुत कम है।

यह मिश्रण कैसे बनता है?

इस में नीचे लिखते दवाइयाँ है।

20ml 0.5% रोपीवाकैथन
40ml सलैन
0.3ml नेरो ऐड्रीनलीन (0.6mg)
40mg टपोमेटरोल (मीथैल प्रणीसलोन ऐसीटैट)
10mg मेटफीन
30mg कीटोरीलाक
1gm सिफेसोलिन

यह निश्चेतना का कोई दुष्प्रभाव है ?

अब तक इसका कोई दुष्प्रभाव नहीं देखा गया है। इसका काफी समय से इस्तेमाल हो रहा है और अनुसंधानों में इसका सुरक्षित होने का प्रमाण भी है।

क्या आप अपना दर्द निवारक इंजेक्शन खुद लगा सकता है ?

आप इस में भाग लेंगे तो आपको यादृच्छिक तरीके से किसी एक समूह में डाला जाएगा। इसके कारण आपको अगर कोई और दर्द निवारक दवा कि आवश्यकता पड़े तो वो आपको अवश्य दिया जाएगा।

यह नयी तरीके से मुझे कितने देर तक दर्द से मुक्ति मिलेगी ?

यह पहले ही दिन से आपका दर्द कम करेगा और आप जल्दी चल भी सकते हैं।

अगर इन सब के बाद भी दर्द हो तो ?

ऐसे स्थिति में आपको दर्द निवारण के लिए दूसरे दवाइयाँ देंगे। आपको मॉर्फिक्लोफेनाक जैसे दवाई दिया जाएगा।

इसमें भाग लेंगे तो क्या करना होगा ?

आपका आपरेशन और बाकी इलाज साधारण तरीके से ही किया जाएगा। केवल दर्द निवारण तरीके में अन्तर है। आपको किसी एक ग्रुप में यादृच्छिकता से डाला जाएगा। आपका दर्द आपने के लिए एक डॉक्टर होगा जो आपका पूरा ख्याल रखेंगे। एक फिजियोथेरापिस्ट आपको चलने में मदद करेंगे। हम यह निरीक्षण करेंगे कि आप कितने समय में 50 मीटर चलेंगे और 10 सीढ़ियाँ चढ़ेंगे। आप किसी भी मुश्किल का अनुभव करें तो यह डॉक्टर को तुरन्त ही बताएं।

क्या हम इस में भाग लेने को राजी होने के पश्चात इस फैसले से मुड़ सकते हैं ?

इस में भाग लेना बिलकुल स्वेच्छिक है और ऑपरेशन के पूर्व किसी भी समय आप अपना फैसला बदल सकते हैं। ऐसे में आपको पहले वाला दर्द निवारक मार्ग इस्तेमाल करेंगे।

हमें इस अनुसंधान के दौरान कोई नयी दुष्प्रभाव या हानी प्रकट हुई तो ?

इसका कोई संभावना नहीं है परन्तू अगर ऐसी कोई घटना हुई तो तुरन्त ही आपको उसका इलाज मिलेगा ।

इस अनुसंधान के खतम होने पर क्या होगा ?

अगर हमें इस नया तरीका बेहतर होने का प्रमाण मिला तो हम इस तरीके को अपनाएँगे । इस सिद्धान्त को हम जर्नल में प्रकाशित भी करेंगे ।

हमारे निजी सूचनाओं को क्या गोपनीय रखा जाएगा ?

बिलकुल गोपनीय रखेंगे ।

इसका परिणित फल ही जर्नल में प्रकाशित करेंगे आपका मेडिकल रेकार्ड्स इस अनुसंधान से जुड़ी व्यक्तियों को निरीक्षण के लिए दिया जाएगा जिसके लिए आपसे कोई अनुमति नहीं लिया जाएगा ।

If you have any further questions, please contact

Dr.Ajith.K,
Department of orthopaedics Unit 2,
Christian Medical College,
Vellore.
Phone no.08489646987
E-mail:ajith_ortho@yahoo.co.in

இந்த ஆய்வில் பங்கு பெறுவதற்கான படிவம்

ஆய்வின் பெயர்:

மூட்டு மாற்று அறுவை சிகிச்சைக்குப்பின் விரைவாக குணமடைய உதவுவது எது? பெரிஆர்டிக்குலர் இன்ஜெக்ஷன் அல்லது எபிடியூரல் போபிவெகைன்.

ஆய்வு வரிசை எண்:

ஆய்வு செய்யப்படுபவரின் பெயர்:

பிறந்த தேதி / வயது (வருடங்களில்):

நான் (ஆய்வு செய்யப்படுபவரின் பெயர்) _____

நான் மேற்குறிப்பிட்ட ஆய்வு பற்றிய தகவல் படிவத்தைப் படித்து புரிந்து கொண்டு மற்றும் சந்தேகங்களைக் கேட்டு தெளிவுபடுத்திக் கொண்டேன். [ ]

இந்த ஆய்வில் பங்கு பெறுவது முழுவதுமாக என் விருப்பத்தைச் சார்ந்த ஒன்று என்றும் இந்த ஆய்வில் இருந்து எப்போது வேண்டுமானாலும் விலகிக் கொள்ளலாம் என்றும் அறிவேன் அதனால் என் மருத்துவம் பாதிக்கப்பட மாட்டாது என்றும் அறிவேன். [ ]

இந்த ஆய்வு சம்பந்தமாக ஏற்படும் எந்த விதமான சேதத்திற்கும் மற்றும் பாதிப்புகளுக்கும் இலவச மருத்துவம் அளிக்கப்படும் என்றும் மற்ற எந்த விதமான பொருளாதார உதவிகள் கிடைக்காது என்றும் அறிவேன். [ ]

நீங்கள் ஆய்விலிருந்து விலகினாலும் ஆய்வு சம்பந்தபட்ட அனைவரும் உங்களின் மருத்துவக் குறிப்பேட்டை உங்களின் முன் அனுமதியின்றி பயன்படுத்துவார்கள். நான் இதற்கு சம்மதிக்கிறேன். [ ]

என்னுடைய தனிப்பட்ட விவரங்கள் மற்றும் மருத்துவ தகவல்கள் முன்றாமவர்க்கு தெரியபடுத்தப்படமாட்டாது மற்றும் அறிவிக்கப்படமாட்டாது என்றும் அறிவேன். [ ]

நான் என் முழு விருப்பத்துடன் இந்த ஆய்வில் பங்குபெற விரும்புகிறேன். [ ]

பெயர்:

கையெழுத்து:

தேதி:

இடது கை பெருவிரல் பதிவு

சாட்சிக்கையெழுத்து:

உறவுமுறை:

தேதி:

இடது கை பெருவிரல் பதிவு

கிருத்துவ மருத்துவக் கல்லூரி

எலும்பு பிரிவு

மூட்டு மாற்று அறுவை சிகிச்சைக்கு பின் விரைவாக குணமடைய உதவுவது பெரிஆர்டிக்குலர் இன்ஜெக்ஷன் அல்லது எபிடியூரல் போபிவெகைன்

ஆய்வு பற்றிய தகவல் படிவம்

மூட்டு மாற்று அறுவை சிகிச்சைக்குப் பின் ஏற்படும் வலியைக் குறைப்பதற்கான முறையில் நடைபெறும் இந்த ஆய்வில் பங்குபெறுமாறு உங்களைக் கேட்டுக் கொள்கிறோம்.

மூட்டு மாற்று அறுவை சிகிச்சைக்குப்பின் ஏற்படும் வலிறை சமாளிப்பதற்கு நடைமுறையில் எபிடியூரல் இன்புயஷன் உள்ளது. இந்த முறையில் அறுவை சிகிச்சைக்குப்பின் முதுகுத் தண்டில் ஒரு சிறிய குழாய் மூலமாக வலிநிவாரணியை 48 மணி நேரத்துக்கு செலுத்தப்படுகிறது. நாங்கள் பின்பற்றுகின்ற இந்த புதிய முறையில் அறுவை சிகிச்சை செய்யும்பொழுதே மருந்துக் கலவையை மூட்டுப் பகுதியில் உள்ள தசைகளில் செலுத்தப்படுகின்றது. இந்த வகையான வலி நிவாரணி நல்ல பலனளிப்பதாக ஆய்வின் மூலம் கண்டறியப்பட்டுள்ளது. இந்த புதிய முறையின் செயல்படுத்தும் திறனை மதிப்பிடுவதற்காக மூட்டு மாற்று அறுவை சிகிச்சை செய்து கொண்டவர்களுக்கு இதனை பயன்படுத்துகிறோம். இதன்மூலம் இந்த புதிய முறையையும் மற்றும் நடைமுறையில் உள்ள எபிடியூரல் இன்புயஷன் முறையையும் மதிப்பிடுகிறோம் அல்லது ஒப்பிடுகிறோம்.

அறுவை சிகிச்சை முறை என்பது ஒரே மாதிரியானது தான். ஆனால் எபிடியூரல் இன்புயுஷனுக்குப் பதிலாக புதிய வலி நிவாரணியை பயன்படுத்துகிறோம். இந்த முறையானது வலியை நீக்குவதிலும் விரைவாக நமது நடைமுறை வாழ்க்கைக்கு திரும்பவும் மற்றும் பிரச்சனையிலிருந்து விரைவாக மீண்டு வர உதவுகிறது. இந்த புதிய முறை பக்க விளைவுகள் அல்லது பாதிப்புகள் அற்றது. எபிடியூரல் இன்புயுஷன் முறையில் உள்ள குமட்டுதல், வாந்தி எடுத்தல் மற்றும் அரிப்பு போன்ற ஒரு சில பக்க விளைவுகள் இந்த முறையில் ஏற்பட வாய்ப்பு இருக்கிறது. இவை தவிர வேறு எவ்விதமான பக்க விளைவுகள் இல்லை.

வலியைக் குறைப்பதற்கான இந்த வலிநிவாரணியில் அடங்கியுள்ள மருந்துகள்.

இந்த பெரிகேப்சுயுலர் மருந்து கலவையில் அடங்கியுள்ள மருந்துகள் பின்வருமாறு:

- 20 மிலி 0.5மூ ரோபிவெக்சின்
- 40 மிலி சலைன்
- 0.3 மிலி நோரட்றேனளின் (0.6)
- 40 மிகி டிபோமெட்ரல் (மெத்தில் பிறட்னிசலோன் அசிடேட்)
- 10 மிகி மோர்பின்
- 30 மிகி கேட்றோலக்
- 1 கிராம் செபாசாளின்

இந்த ஆய்வில் பக்கவிளைவுகள் ஏதேனும் உண்டா?

இல்லை. இந்த புதிய முறையினால் எவ்விதமான பக்க விளைவுகள் இல்லையென்பதை நிறைய ஆய்வுகள் மூலம் நிருபிக்கப்பட்டுள்ளது.

உங்களது அறுவை சிகிச்சைக்குப்பின் எந்த முறையினை வலிநிவாரணியாக தேர்ந்தெடுப்பீர்கள்.

நீங்கள் இந்த ஆய்வில் பங்கு பெற விரும்பினால் ஆய்வாளரின் மூலம் தேர்ந்தெடுக்கப்பட்டு எபிடியூரல் இன்புயுஷன் அல்லது பெரிகெப்சுயுலர் மருந்து நிவாரணியாக கொடுக்கப்படும். இவை தவிர வேறு ஏதேனும் வலி நிவாரணி தேவைப்பட்டால் கொடுக்கப்படும்.

பெரிஆர்டிக்குலர் வலிநிவாரணி எவ்வளவு நேரம் நிவாரணியாக வேலை செய்யும்?

இந்த பெரிஆர்டிக்குலர் வலி நிவாரணி உங்களது அறுவை சிகிச்சைக்குப்பின் உடனடி வலிநிவாரணியாக நன்றாக வேலை செய்யும் மற்றும் முடிந்த வரையில் நீங்கள் நடப்பதற்கு ஊக்கப்படுத்தப்படுவீர்கள். இம்முறை நன்றாக வேலை செய்யும் என்பதை ஆய்வின் மூலம் நிருபிக்கப்பட்டுள்ளது.

இம்முறையில் வலி குறையவில்லையென்றால?

இந்த வலிநிவாரணியே போதுமானதாக இருக்கும். இதையும் மீறி வலி இருந்தால் கூடுதலாக வலிநிவாரணி கொடுக்கப்படும் அது உங்களுக்கு வலியை குறைக்க உதவும். மேலும் கிருமிநாசினி மருந்து (T. அசெக்லோடினெக்) கூடுதலாக கொடுக்கப்படும்.

நீங்கள் பங்கு பெற விரும்பினால்?

நீங்கள் எந்த வகையான மருந்தினை பெறுவீர்கள் என்பதை தேர்ந்தெடுக்கப்பட்டு அளிக்கப்படும். மற்ற சிகிச்சைகள் தொடரப்படும்.

அறுவை" சிகிச்சைக்குப்பின் உங்கள் மருத்துவரால் தொடர்ந்து கண்காணிக்கப்படுவீர்கள். உங்களுக்கு வலி அல்லது வேறு ஏதேனும் பிரச்சனைகள் இருந்தால் மருத்துவர் உங்களுக்கு உதவி செய்தார். உடற்பயிற்சியாளர் (Physiotherapist) அறுவை சிகிச்சைக்குப்பின் நடப்பதற்கு உங்களுக்கு பயிற்சி அளிப்பார். நீங்கள் 50 மீட்டர் தூரம் நடப்பதற்கும் மற்றும் 10 படிகள் ஏறுவதற்கும் எடுத்துக் கொள்ளும் நேரம் கண்காணிக்கப்படுகிறது.

நீங்கள் மருத்துவமனையிலிருந்து விடுவிக்கப்பட்டபின் மூன்று மாதம் கழித்து மறுஆய்விற்கு (review) அறுவை சிகிச்சையாளரின் அழைப்பிற்கிணங்க வரவேண்டும்.

உங்களுக்கு ஏதேனும் பிரச்சனைகள் ஏற்பட்டாலும் எந்த நேரமானாலும் கீழே குறிக்கப்பட்டுள்ள மருத்துவரை அணுகலாம்.

இந்த ஆய்வு தொடங்கியபின் விலக முடியுமா?

நீங்கள் இந்த ஆய்வில் பங்கு பெறுவது உங்கள் விருப்பமே. ஆனால் நீங்கள் அறுவை சிகிச்சைக்குமுன் தேர்ந்தெடுக்க வேண்டும். நீங்கள் அப்படிச் செய்யும்போது உங்கள் மருத்துவத்தில் எந்த மாற்றமும் இருக்காது. உங்களுக்கு நடைமுறையில் உள்ள வலிநிவாரணியே கொடுக்கப்படும்.

இந்த ஆய்வின் மூலம் உங்களுக்கு ஏதேனும் சேதம் ஏற்பட்டால் என்ன செய்யப்படும்?

இந்த ஆய்வின் மூலம் எந்த விதமான சேதம் மற்றும் ஒவ்வாமை ஏற்படாது. எனினும் உங்களுக்கு ஏற்பட்டால் தகுந்த முறையில் மருத்துவம் அளிக்கப்படும்.

ஆய்வின் முடிவில் ஏற்படுவது என்ன?

ஒருபக்க மூட்டு மாற்று அறுவை சிகிச்சை செய்து கொள்ளும் நோயாளிக்கு இந்த ஆய்வின் மூலம் பெரி-ஆர்டிக்குலர் இன்ஜெக்ஷன் அல்லது எபிடியூரல் இன்புயுஷன் எந்த முறை சிறந்தது என்று ஆய்வு செய்யப்பட்டு மருத்துவத்துறை பத்திரிக்கையில் வெளியிடப்படும்.

உங்களுடைய தனிப்பட்ட விவரங்கள் வெளியிடப்படுமா?

இந்த ஆய்வின் முடிவுகள் மருத்துவ பத்திரிக்கையில் வெளியிடப்படும் மற்றும் உங்களைப்பற்றிய அடையாளங்கள் அல்லது தனிப்பட்ட விவரங்கள் வெளியிடப்படமாட்டாது. ஆனால் இந்த ஆய்வு சம்பந்தபட்ட அனைவரும் உங்களின் மருத்துவக் குறிபேட்டை உங்களின் முன் அனுமதியின்றி பயன்படுத்துவார்கள்.

மேலும் விவரங்களுக்கு:

மருத்துவர் **K. அஜித**
எலும்பு பிரிவு – II
கிருத்துவ மருத்துவக் கல்லூரி
வேலூர் - 632 004
போன்: 08489646987
இமெயில்: ajith_ortho@yahoo.co.in